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alvimtrabalhos@hotmail.com.br

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Luciana Danielli de Araújo
CRB-7 5024
ldanielli@uol.com.br

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Brazilian Journal of Videoendoscopic Surgery

Editorial

Cohort and Case-Control Studies in the Evidence-Based Medicine Era

Estudos de Coorte e de Caso-Controle na Era da Medicina Baseada em Evidência

MARCO AURÉLIO PINHO DE OLIVEIRA[1]; RAPHAEL CÂMARA MEDEIROS PARENTE[2]

[1] Doctorate in Epidemiology from the Institute of Social Medicine of the University of the State of Rio de Janeiro (UERJ). Chief, Gynecology Division, UERJ; [2] Doctorate in Gynecology (Human Reproduction) from the Federal University of the State of São Paulo (UNIFESP). Master's in Epidemiology from the Institute of Social Medicine of the University of the State of Rio de Janeiro (UERJ).

A cohort study is an observational study where individuals are classified (or selected) according to exposure status (exposed or unexposed), and are followed to evaluate the incidence of disease in a given period of time. Cohort studies can also be used to assess the risks and benefits of using a given medication.

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1. The following are the principal phases of a cohort study: Read phonetically

a. Identify healthy persons at baseline;

b. Assemble groups of subjects exposed and not exposed;

c. Follow-up of the cohort to evaluate the incidence of the disease being studied in two groups;

d. To compare the incidence (risk) in each cohort;

2. Cohort studies have certain advantages:

a) They can discern the temporal relationship between exposure and outcome due to the fact that the exposure precedes the outcome;

b) Can be used to evaluate multiple outcomes;

c) They permit the direct calculation of measures of incidence in cohorts of exposed and unexposed subjects;

d) The status of the outcome does not influence the measurement of exposure status or selection of subjects (concurrent cohort/competing cohort);

e) They are less subject to selection bias than case-control studies;

f) Some studies also allow multiple exposures can be assessed (cohorts of the general population, population groups restricted).

3. Cohort studies have some disadvantages:

a) As with case-control studies, it is an observational study, with all the weaknesses of an observational design (when compared to experimental studies – randomized clinical trials)

b) It may be inefficient for studying rare diseases or those with long latency periods;

c) Generally expensive and difficult to operationalize (in etiological studies);

d) The loss of participants during the follow-up may compromise the validity of results.

Overview of a cohort study:

A cohort study is a specific type of observational study design that has a higher level of evidence than the other observational studies such as case reports and case series, case-control and cross-sectional studies, but a lower level of evidence than experimental studies.

Cohort studies are performed in three basic steps:

1. Assemble or identify groups of individuals exposed and unexposed that are free of the disease being studied;

2. Observe each cohort over time to assess the development of the disease in the groups studied;

3. Compare the risk of developing the disease among groups of exposed and unexposed subjects.

The first step in a cohort study is to identify groups of exposed and unexposed subjects. A cohort is a group of people, taken from the study population, which shares a common experience or condition and whose outcome is unknown at the beginning of the study. In cohort studies, researchers observe exposure status, which occurs "naturally" (i.e., the researcher does not actively interfere). In contrast, in clinical trials, the researchers experimentally apply the exposure to the study participants.

Example: The investigators/researchers want to evaluate whether smoking causes cancer of the cervix. They recruit 2,000 women with an intact uterus. The researchers use a questionnaire to determine the smoking status of all study subjects and then divide the study population into a cohort of smokers and another group of nonsmokers.

They watch each cohort over time and compare the risks of the incidence of cervical cancer between the two groups.

Cohort studies usually focus on the incidence of cases of the disease that occur during the follow-up. To achieve this goal, researchers typically exclude individuals who have the disease present at the beginning of a cohort study (in our example, those who have had cervical cancer would be excluded). The evaluation of the results of the incidence of the disease helps to establish that the exposure of interest precedes the outcome (disease) and, therefore, may represent one cause of the disease.

In the cohort studies, the researchers observe the exposure of interest. As a result, exposed and unexposed individuals may vary depending on other features. In our example, patients who smoke may be more likely to be carriers of HPV, a known risk factor for cervical cancer. The concept that factors other than the exposure may influence the results of the study is called a confounding factor.

Accurately obtaining the study data:

From the moment that the investigators decide what specific variables and outcomes will be used in the study, they should use the most accurate methods possible to measure these characteristic and applying them to all study participants. Important considerations in the measurement of the study data are the validity of measurements, the time between the measurements, and the availability of uniform measures for the population under study.Listen

Validity of measurements:

The validity of a measurement refers to how close the measured data represent the real data. It should be as close to reality as possible.

Time between measurements:

The right time interval between the exposure measurements and the outcome will depend on prior knowledge about the outcome. In some cases, researchers may be interested in the association between recent exposure and disease, particularly if there is concern that exposure may change during the study. For example, non-steroidal anti-inflammatory drugs (NSAIDs) can cause rapid constriction of the renal arteries, leading to an increased risk of acute kidney injury. Researchers studying the relationship between NSAIDs and use of medications and acute kidney injury can concentrate their efforts in obtaining a valid estimate of recent use of NSAIDs in the occurrence of acute kidney injury. The verification of recent use of medication can be obtained by frequently updating the status of each participant during the study. There are other examples where the association of interest is the relationship between long-term exposure and the disease. For example, smoking can cause damage to a kidney transplant by gradual thickening of the intima and media of the arterial wall. The researchers in this study can, therefore, choose to evaluate smoking history over the long term, quantified as the number of pack-years of smoking after transplantation. Cohort studies are not ideal for the study of very recent or very remote exposures. Remote exposures may change over time, obscuring their relationship to the outcome of interest. Very recent exposures can confound the presumed temporal relationship between the exposure and outcome.

Retrospective versus prospective data collection (prospective cohort vs. retrospective cohort):

Cohort studies can be classified as concurrent (prospective, classic) or non-concurrent (retrospective). In non-concurrent studies, all the information about exposure and outcome has occurred before the start of the study. In concurrent studies, the exposure may (or may not) have already occurred, but the outcome has not occurred.

The problems with non-concurrent studies are: information bias and the inability to control confounding variables (lack of information). A prospective study involves collecting new data often for the purpose of addressing a specific issue. The distinction between retrospective and prospective studies is essentially descriptive; in general it does not generate any impact on the plan of analysis or on the results of the study, besides those already mentioned.

A major advantage of cohort studies is the ability to assess multiple outcomes. Researchers of cohorts under study are free to study another outcome, as long as the subjects under study were free of that outcome of interest when the study began. As an example, in a study that evaluated the relationship between smoking and kidney transplants, the investigators could also study whether smoking was associated with the development of kidney or bladder cancer.

One of the largest cohort studies ever conducted was the Nurses Health Study (NHS), which recruited 127,000 nurses, between 30 and 55 years of age. Through questionnaires sent every two years, the NHS evaluated various variables among the nurses such as: health, prescription and nonprescription medication use, social habits, eating and physical activity habits, among others. This open cohort study design allowed the creation of multiple cohort studies that assessed risk factors for a wide range of diseases, including cancer, heart disease and fractures, among various other outcomes. These studies have the ability to discern the temporal relationship between exposure and outcome.

Unlike cross-sectional studies, cohort studies can reveal temporal relationships between the exposure and the outcome, as long as a reasonable time interval has elapsed between measurement of exposure and the occurrence of the outcome. The existence of a temporal relationship strengthens the evidence that the exposure is a possible cause of the disease. Establishing a temporal relationship between exposure and outcome is inherent in the study design and cannot be solved by any statistical methodology.

Disadvantages of cohort studies:

a) Cohort studies are observational studies, and therefore are subject to confounding factors. That is, other factors that are related to the exposure of interest may explain some or all associations that are observed.

b) Inability to examine diseases that are rare or that have a long latency. Cohort studies may be inefficient if the outcome is rare or the disease has a long latency period.

Example 1: Researchers want to investigate whether use of talc in childhood increases the risk of ovarian cancer in adulthood. Using a cohort study design, one approach could be to recruit cohorts of children with and without a history of using of talc and follow these groups for the subsequent development of ovarian cancer. However, many years of follow-up would probably be necessary for the development of cancers in adulthood. In this example, the long latency period between exposure and outcome would make study this very expensive and logistically difficult.

Example 2: The researchers intend to investigate whether sleeping in the prone position is a potential cause of sudden infant death syndrome (SIDS) in babies.

Using a cohort approach, they could identify a cohort of children who sleep in the prone position and a cohort of children who sleep in the supine position and then compare the risks of SIDS between the cohorts. However, SIDS is relatively rare, requiring the recruitment of thousands of newborns to accumulate enough cases of SIDS to be able to draw meaningful conclusions. In this case, a case-control study would be more appropriate. It is possible to overcome the limitations of the cohort studies with rare diseases and high latency using data sources to facilitate the study of large populations.

Cohort studies to evaluate the use of medications:

Cohort studies can be an important tool to study the risks and benefits of a certain medication. These studies may provide specific information about medications that cannot be obtained from clinical trials. First, cohort studies can assess the risks and benefits of drugs in populations that tend to be excluded from randomized trials such as patients with physical and mental disabilities, people end-stage renal disease (ESRD), or those with liver disease. Second, cohort studies can detect side effects and evaluate clinical outcomes of licensed drugs by the *Study* of medication users' data from very large cohorts of patients who obtain their medications from pharmacies with sophisticated information systems. The main limitation of observational studies of drug use is the difficulty in

separating the effect of a medication from the underlying characteristics of those using the drug. For example, observational studies on hormone therapy (HT) have found that women who used Hormone Replacement Therapy (HRT) have lower risks of cardiovascular events compared with women who did not. Clinical trials have not corroborated these results; rather, they show an increased risk of cardiovascular events in HRT users.

The second disadvantage of pharmaco-epidemiology studies is their tendency to assess chronic users of medication, rather than new users. Despite their limitations, pharmaco-epidemiology studies remain an important tool to evaluate drugs that are used in clinical practice.

Incidence proportion versus incidence rate:

Cohort studies usually involve comparison of two cohorts, but may have only one (which can be compared to other published informal groups or to historical data) or more than two (for example, different groups of serum levels of specific serum marker or different doses of a drug). Regardless of the number of cohorts, one must first calculate the incidence of disease in each group, as an incidence proportion or as an incidence rate. This should be done taking into account the time that each participant was followed in the study, generating for each individual a person-time product. Failing to take the person-time product into consideration can lead to a bias, which constitutes a systematic distortion of the true result. For example, suppose that in certain study of smokers and nonsmokers, smokers leave the study more frequently than non-smokers (smoking could predispose subjects to quit the study) so that smokers end up being followed for less time than non-smokers. In these circumstances, it would be possible to observe a lower incidence of diseases among smokers, simply because they are followed for less time.

The follow-up in the denominator of the incidence rate standardized disease rates temporally, eliminating this potential problem.

Relative Risk:

Once we determine the incidence of disease in each cohort, we can compare these incidences. Many types of comparisons are possible; the most common are the relative risk and attributable risk.

The relative risk is defined as the incidence (proportion or rate) in a cohort divided by the incidence in the reference cohort. For example, in a hypothetical study, the incidence rate of failures of kidney transplants is 82.6 per 1,000 person-years among smokers and 55.3 failures per 1,000 person-years among nonsmokers.

Using non-smokers as the reference cohort, the relative risk would be:

$$\frac{\text{82.6 failures per 1000 person-years}}{\text{55.3 failures per 1000 person-years}}$$

RR = 1.49 (comparison between smokers and nonsmokers)

The relative risk can also be expressed using smokers as the reference cohort:

RR = 0.67 (comparison between the nonsmokers and smokers)

*

Both relative risks are correct. You can choose either group to be the reference group. Note that the relative risk has no units.

The interpretation of the first relative risk of 1.49 would be, "transplanted kidneys in patients who smoke are 49% more likely to develop renal insufficiency relative to non-smokers." We say they are "49% more likely" because 1.49 is 49% greater than 1.0.

An interpretation of the second relative risk was non-smokers with a transplanted kidney are 33% less likely to develop renal insufficiency then smokers. The second calculation of relative risk shows an association with a lower risk of disease, because the value is less than 1.0.

Why is smoking associated with a 49% higher risk of failure of the transplant, but among non-smokers, with only a 33% lower risk of failure? In other words, why aren't the relative risks additively symmetric for the same exposure? Note that relative risks – as with all proportions – can take values ranging from 0 to infinity, while 1.0 defines the value of unity. It is more difficult to obtain the relative risks that are much less than 1.0, because they are limited to 0.

For this reason, the relative risks that are below 1.0 indicate stronger associations than the symmetric associations that are larger than 1.0.

Attributable Risk (also known as "risk difference" or "excess risk"):

The attributable risk is defined as the incidence (proportion or rate) in a cohort minus the incidence of

the other group. For the example of renal transplant and smoking, the attributable risk of transplant failure comparing smokers with nonsmokers would be: 82.6 transplant failures per 1,000 person- years (smokers) - 55.3 transplant failures per 1,000 person-years (non-smokers) = 27.3 transplant failures per 1,000 person-years.

Note that the attributable risk, unlike the relative risk, retains the same units that are being compared.

If the exposure of interest is a cause of the disease, the attributable risk describes the amount of additional or extra risk which is due to the exposure. For example, if smoking actually causes the failure of a kidney transplant, then the interpretation of attributable risk for smoking would be "there is an additional risk of renal insufficiency in 27.3 kidney transplants for each 1,000 person-years in transplant recipients who smoke."

CASE-CONTROL STUDIES

To introduce the concept of case-control study, we can ask the following question:

Does alcohol consumption increase the incidence of pancreatic cancer? A case-control study published in 1989 showed a significant increase of the disease in those who consumed larger quantities of beer.[1]

Considering this possibility, we can design a hypothetical case-control study, as laid out below.

First let's consider what would be the approach of a cohort study for this research question. The researchers were able to identify a cohort of 1,000 adults who drink alcohol regularly and another cohort of 1,000 adults who do not drink alcohol. After exclusion of adults with problems in the pancreas at the beginning of the study, researchers observed each cohort for the development of pancreatic cancer (PC) during follow-up. The data obtained using this approach are presented in Table 1.

These data, comparing adults who consume alcohol with those who do not consume, do not suggest a difference in the incidence of pancreatic cancer, but there are too few cases of pancreatic cancer in this study to reach a meaningful conclusion. In this example, the cohort study design is inefficient because the outcome (pancreatic cancer) occurs infrequently.

And if the cohort study design were reversed? If instead of starting with exposed cohorts (those who consume alcohol) and unexposed (those who do not consume alcohol), researchers began identifying adults with and without the outcome of interest, i.e., cancer of the pancreas?

We can imagine a study in which researchers identified 1,300 adults with pancreatic cancer in a given country in a good quality electronic database. They used the same database to determine whether the cases were regular consumers of alcohol before they developed pancreatic cancer.

The data in Table 2 show an apparently high proportion (77%) of alcohol consumption in patients suffering from pancreatic cancer. The next step would be to compare this figure with patients matched according to age, gender, etc. but who do not have pancreatic cancer.

The researchers used the same database to obtain the data presented in Table 3. This table shows that the proportion of adults without PC and that consume alcohol (71%) is slightly lower than the group with PC, which speaks in favor of alcohol being a risk factor for pancreatic cancer).

Table 1 – *Beer Consumption and Pancreatic Cancer: a cohort study.*

	Pancreatic Cancer		
Consumes Beer	**Yes**	**No**	**Total**
Yes	5	995	1.000
No	6	994	1.000

Table 2 – *Consumption of alcohol among 1300 patients with Pancreatic Cancer.*

	Alcohol Consumption	
Yes	1000	(77%)
No	300	(23%)
Total	1300	

Table 3 – *Consumption of alcohol among 4500 adults without Pancreatic Cancer.*

	Alcohol Consumption	
Yes	3200	(71%)
No	1300	(29%)
Total	4500	

The study results are best appreciated by presenting the data pertaining to patients and unaffected individuals together. The data in Table 4 illustrate the concept. The case-control study starts with patients and unaffected individuals, and then checks their exposure status prior to the development of the disease. Correctly carried out case-control studies can be used to suggest important causal relationships.

Case-Control Studies

The first step to achieving a successful case-control study is the careful selection of cases and controls.

SELECTION OF CASES

A. Carefully Specify the Disease in question

A very specific definition of the disease is extremely important in case-control studies to ensure that the disease in question is really present among individuals who are being defined as cases. This strategy may require the exclusion of individuals with milder forms of a particular disease (or include them and improve the diagnostic accuracy) in order to concentrate on more advanced cases, which can be diagnosed with greater certainty. On the other hand, it is generally less important to devote extra resources to confirm that the control subjects are truly free of the disease in question. Case-control studies usually investigate rare diseases (low incidence, difficult to study in a cohort), which are unlikely to be present in individuals randomized to the control group.

B. Selecting incident cases

Typically, the goal of case-control studies is to study the development of the disease. Therefore new or incident cases of the disease are usually preferred than the chronic cases of long duration. One reason for focusing on incident cases is to establish whether the exposure of interest (e.g., alcohol consumption) was clearly present before the onset of the disease. For example, the selection of adults with long-standing pancreatic cancer may complicate proof of alcohol consumption before the development of their disease (e.g., they may have started to drink after learning of their disease some years ago but not before – which is more difficult differentiate with the passage of time). A second reason for the choice of incident cases is that the alternative, the selection of chronic cases, may hinder the study of the etiology of the disease if it affects the survival of the individual. To illustrate this concept, consider a case-control study that evaluates whether the serum markers of oxidative stress are related to cerebral vascular accidents (CVA). The researchers start by identifying individuals with stroke (cases) and those without stroke (controls) and then measure the oxidative stress markers in serum samples that were collected 10 years ago.

If the researchers selected as cases individuals with chronic stroke, they would be studying the "survivors of stroke," whose survival could be related to certain healthier characteristics, which would be reflected in lower levels of serum markers of oxidative stress. The result could be an artificial negative association – the higher the levels of the markers, the lower the chances of stroke – between serum markers of oxidative stress and stroke.

SELECTION OF CONTROLS

A. Select controls from the same population base as the cases

Case-control studies compare the frequency of exposure (e.g. alcohol consumption) among individuals who have a disease and individuals who do not have the disease.

Table 4 – *Consumption of alcohol and pancreatic cancer: case-control study.*

Prior Consumption of Alcohol	Pancreatic Cancer		Total
	Yes (N=1300)	No (N=4500)	
Yes	1000 (77%)	3200 (71%)	4.200
No	300 (23%)	1300 (29%)	1.60

The interpretation of the results of a case-control study depends on the assumption that the control group was obtained from a population suitable for estimating the frequency of exposure. The overall objective is to obtain controls that derive from the same population base as the cases.

In the example of the study of pancreatic cancer (PC), the cases in the study could have been selected from the national health system in Sweden, where the database is of high good quality and prevalence of alcohol consumption is relatively high. If researchers, instead of selecting the control group from Sweden, were to select the controls from a different country, say a Muslim countries, where alcohol intake is less common, we would have observed a higher proportion of alcohol consumption among cases (of Sweden, who on average drink more alcohol), leading to the false conclusion that alcohol intake is more common among patients with PC. Listen.

B. The controls should have the same chance of being selected as cases if, instead of healthy, they were or became sick

In the study of PC in Sweden, the controls had the same chance of being diagnosed as cases because they were part of the same health system that captured patients using diagnostic codes. One method to ensure that cases and controls derive from the same underlying population and that will have the same chance of being diagnosed with a disease is to do a nested case-control study. This study design selects cases and controls from a larger cohort study. For example, the Cardiovascular Health Study (CHS) recruited 5,800 elderly from four communities and performed serologic evaluation of renal function among all participantes.[2]

A case-control study nested in the CHS can easily identify cases with renal dysfunction and controls with normal renal function based on laboratory data that were obtained using identical methods. The researchers could then try to estimate the frequency of use of a certain anti-inflammatory drugs (which could impair the kidneys) among the cases and the controls using previously collected data on prescription practices.

C. Pairing

The case-control studies often use pairing to increase the degree of similarity between cases and controls.

In the study of PC, an example of pairing would be to first choose an individual with PC and then identify a control that does not have PC, but that is the same age and sex of that case.

Using appropriate analytical techniques, pairing can reduce the possibility of other factors that disrupt the association between exposure and outcome (called confounding; e.g., in the case of PC, smoking could increase the chance of pancreatic cancer and those who drink alcohol usually smoke more; i.e. the risk factor for PC in those who drink alcohol would actually be smoking, which is more prevalent in those who drink).

D. Number of controls

In a case-control study, the disease of interest is usually rare, so finding cases is often the limiting step of the process. There are no specific rules about the number of controls that are needed in each study; however, more controls generally provide a more accurate estimate of the frequency of exposure in the control group and can increase the power of analysis (the ability to detect an association if it is actually present). Financial resources usually determine the number of controls that can be selected for each case. There is a sharp increase in the power of the study when more controls are added, until about three to four controls per case, the point at which adding more controls has little effect on the power of the study.

ADVANTAGES OF CASE-CONTROL STUDIES

A. Case-control studies may be ideal for studying rare diseases or diseases with long latency period.

Cohort studies and randomized clinical trials can be difficult to execute when the outcome of interest is rare or the latency period between exposure and outcome is long (e.g., it may take years between alcohol intake and the appearance of pancreatic cancer).

Case-control studies can be useful to study the processes in which the period of time observed between exposure and the development of the disease is particularly long and if the previous data on exposure are available or can be easily obtained.

For example, it may take years for certain dietary factors, such as fish oil, to produce cardiovascular benefits. A case-control study could

identify individuals with and without coronary heart disease and then question them regarding the frequency and amount of prior consumption of fish oil (obviously controlling for confounding factors).

B. Case control studies allow the study of multiple exposures

Cohort studies identify individuals based on their exposure status, and subsequently follow the cohorts to observe the outcome of interest. In contrast, case-control studies identify individuals based on their disease status, allowing the study of multiple exposures within a pre-defined group of cases and controls. For example, since PC cases and controls without PC are identified, the study investigators could explore other risk factors for PC.

DISADVANTAGES OF CASE-CONTROL STUDIES

A. Observational study design

As in cohort studies, case-control studies are observational studies designs and are subject to confounding. The cases may differ from the controls with regard to factors other than the exposure of interest. The confounding occurs when another factor, other than the exposure of interest, distorts the association between exposure and outcome, thus limiting the inference that the exposure causes the disease.

B. Recall bias

As in cohort studies, case-control studies can obtain the study data using a variety of sources including medical records, questionnaires, interviews and laboratory tests. As in cohort studies, case-control studies seek measurements that are valid, accurate and uniform for the exposure and for the outcome. An important consideration for the measurements in case-control study is the use of interviews or questionnaires to check the status of prior exposure, because these procedures can lead to a specific type of bias known as recall bias. Recall bias occurs when cases and controls remember their exposure status differently. With the PC study, cases with pancreatic cancer might remember having drunk more alcohol than the healthy controls (because those who are ill end up looking harder for something to blame).

The best solution for minimizing the recall bias in case-control studies is the use of data that were collected in a systematic manner, before the development of disease (e.g., organized and complete medical records used in an efficient healthcare system).

C. Case-control studies only provide information about the relative risk (odds ratio) of the disease

Cohort studies can determine the incidence of disease among exposed and unexposed individuals and then compare the incidence between the two groups using a ratio (relative risk) or a difference (attributable risk). Case-control studies can provide only an estimate (approximation) of relative risk. They cannot be used to calculate attributable risk, nor can be used to calculate the specific incidence of the disease in any group.

ANALYSIS OF DATA IN CASE-CONTROL STUDIES

A. Theory of the odds ratio (OR)

The data from the case-control study of PC showed that 77% of adults with PC have a history of alcohol intake and that 71% of adults without PC possessed this same history. Usually we are interested in the question "what is the risk of pancreatic cancer comparing adults who drink alcohol to those who don't?" We can estimate this information based on data from case-control studies using the odds ratio. To develop the concept of odds ratio, imagine that we have an unlimited funding and resources for studying the adults in the Swedish health system.

We carried out a huge cohort study on alcohol consumption and pancreatic cancer.

Hypothetical data are presented in Table 5.

After recruiting more than 200,000 individuals in the hypothetical cohort study, we can calculate the incidence (proportion) of PC in each group:

Incidence in the group that consumes alcohol = 1000/150,000 = 0.66%

Incidence in the group without alcohol consumption = 300/55,300 = 0.54%

As we are analyzing a hypothetical cohort study, we can use the incidence (proportion) to calculate the relative risk of pancreatic cancer in those who drink alcohol = (0.66/0.54) = 1.22. An interpretation of the relative risk would be "alcohol intake is associated with an increased risk for

Table 5 - *Alcohol consumption and pancreatic cancer: a cohort study.*

Prior Alcohol Consumption	Pancreatic Cancer		Total
	Yes (N=1300)	No (N=4500)	
Yes	1000	150.000	151.000
No	300	55.000	55.300
Total	1300	205.000	206.300

pancreatic cancer of 22%." Comparing data from cohort and from case-control studies, we see that the 4,500 controls represent only a fraction of 205,000 individuals who have PC. In the case-control study, researchers selected the 4,500 individuals of the control group based on the resources available, the study power they were seeking, and what was practical for them to execute. This "arbitrary" selection of 4,500 controls made it impossible to calculate the true incidence of pancreatic cancer among those exposed or not to the ingestion/ consumption of alcohol.

We cannot affirm that the incidence of pancreatic cancer in those who drank alcohol is 1000 / 4200 = 23.8% (see Table 4). This incidence is much higher than the actual incidence of 0.66%, and it would be different depending on the number of controls chosen by the investigator. Likewise, we cannot say that the incidence of pancreatic cancer among adults who do not drink alcohol is 300 / 1600 = 18.7%, for the same reason. Since the error in estimating the incidence is similar in the exposed and unexposed, the ratio of these (false) incidences approximates the relative risk for the disease. This ratio of (false) incidences is not exactly a relative risk, and instead has a different name, the odds ratio. The odds ratio is the principal measure of risk in a case-control study.

B. Practical calculation of the odds ratio (OR)

In fact, the odds ratio is calculated using the number of controls (people without disease) as the denominator. Considering the data from case-control study of pancreatic cancer (Table 6):

Equally correct interpretations of the odds ratio include:

1. Alcohol consumption is associated with a 35% greater chance of PC.

2. The chances of PC are 35% higher among those who drink alcohol compared with those who do not.

3. The odds ratio of PC is 1.35, comparing those who drink alcohol with those who do not drink alcohol.

There is a simple method for calculating the odds ratio for data obtained from case-control studies. First, there should be a contingency table with "with the disease / without the disease" headings at the top and "exposed / not exposed" on the left side. Given this configuration, the table cells are referred to as a, b, c, and d, as shown in the table below (Table 7).

The odds ratio is calculated from this table as (a x d) / (b x c).

Note that no adjustment was made for other factors in this study such as age, race or sex.

As a result, this odds ratio is also called the "gross odds ratio" or "unadjusted odds ratio".

Table 6

Prior Alcohol Consumption	Pancreatic Cancer		Total
	Yes (N=1300)	No (N=4500)	
Yes	1000 (77%)	3200 (71%)	4.200
No	300 (23%)	1300 (29%)	1.600

The odds ratio is calculated as (1.000 / 3.200) / (300/1300) = 1.35.

Table 7

Prior Alcohol Consumption	Pancreatic Cancer		Total
	Yes (N=1300)	No (N=4500)	
Yes	a. 1000	b. 3200	4.200
No	c. 300	d. 1300	1.600

The odds ratio is calculated as (1000 x 1300) / (3200 x 300) = 1.35.

C. Odds ratio and Relative Risk

Using the approach of the cohort study, it was found that the relative risk (RR) of PC, comparing those who drink alcohol with those who do not, was 1.22. Using a case-control approach, it was observed that the odds ratio of PC, comparing with those who drink alcohol with those who do not, was 1.35. These estimates are similar, but not exactly the same. The main factor that determines the agreement between relative risk and odds ratio is the rarity of the outcome in question. The lower the prevalence in the population, the greater the agreement between OR and RR. In the example of alcohol consumption, pancreatic cancer is relatively rare in the population, as there are only 1,300 cases among 206,300 individuals (prevalence = 0.63%). There is no specific cutoff value to define "rare," but generally case-control studies with the prevalence of disease <5% will provide an odds ratio that closely approximates the relative risk.

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Correspondence Address:
MARCO AURELIO PINHO DE OLIVEIRA
Rua Coelho Neto, 55 / 201
Laranjeiras - Rio de Janeiro - RJ
Tel.: (21) 9987-5843
E-mail: maurelio@infolink.com.br

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Editorial

Estudos de Coorte e de Caso-Controle na Era da Medicina Baseada em Evidência

Cohort and Case-Control Studies in the Evidence-Based Medicine Era

MARCO AURÉLIO PINHO DE OLIVEIRA[1]; RAPHAEL CÂMARA MEDEIROS PARENTE[2]

[1] Doutor em Epidemiologia pelo Instituto de Medicina Social da Universidade do Estado do Rio de Janeiro. Chefe do Setor de Ginecologia da UERJ; [2] Doutor em Ginecologia pela UNIFESP (Reprodução Humana). Mestre em Epidemiologia pelo Instituto de Medicina Social da Universidade Estadual do Rio de Janeiro.

Um estudo de coorte é um estudo observacional onde os indivíduos são classificados (ou selecionados) segundo o status de exposição (expostos e não expostos), sendo seguidos para avaliar a incidência da doença em determinado período de tempo. Os estudos de coorte também podem ser utilizados para avaliar os riscos e benefícios do uso de determinada medicação.

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1. As fases principais de um estudo de estudo de coorte são as seguintes:

a. Identificar as pessoas sadias no início do estudo;

b. Montar grupos de indivíduos expostos e não expostos;

c. Seguimento da coorte para avaliação da incidência da doença a ser estudada nos dois grupos;

d. Comparar a incidência (risco) em cada coorte.

2. Os estudos de coorte têm certas vantagens:

a) Podem discernir as relações temporais entre a exposição e o desfecho devido ao fato da exposição preceder o desfecho;

b) Podem ser usados para avaliação de desfechos múltiplos;

c) Permitem o cálculo direto das medidas de incidência nas coortes de expostos e não expostos;

d) O status do desfecho não influencia a medida do status de exposição ou seleção de indivíduos (coorte concorrente);

e) São menos sujeitos a viéses de seleção do que os estudos de caso-controle;

f) Alguns estudos permitem ainda que várias exposições possam ser avaliadas (coortes de população geral ou de grupos populacionais restritos).

3. Os estudos de coorte têm algumas desvantagens:

a) É do tipo observacional (assim como o caso-controle), trazendo todas as fragilidades do desenho observacional (quando comparados aos estudos experimentais – ensaios clínicos randomizados);

b) Pode ser ineficiente para o estudo de doenças raras ou aquelas com longos períodos de latência;

c) Geralmente caros e difíceis de operacionalizar (em estudos etiológicos);

d) A perda de participantes ao longo do seguimento pode comprometer a validade dos resultados.

Visão geral do projeto de um estudo de coorte:

Os estudos de coorte são um tipo específico de desenho de estudo observacional que possuem um nível de evidência maior que os outros observacionais tais como: série e relato de casos, caso-controle e estudos transversais (mas menor nível de evidência que os estudos experimentais).

Os estudos de coorte são realizados em três etapas fundamentais:

1. Montar ou identificar grupos de indivíduos expostos e não expostos que são livres da doença em estudo;

2. Observar cada coorte ao longo do tempo para a avaliação do desenvolvimento da doença nos grupos estudados;

3. Comparar os riscos de surgimento da doença entre os grupos de expostos e não-expostos;

O primeiro passo para um estudo de coorte é identificar grupos de expostos e de não expostos. Uma coorte é um grupo de pessoas, oriundas da população em estudo, que partilha uma experiência comum ou condição e cujo resultado é desconhecido no início do estudo. Nos estudos de coorte, os pesquisadores observam status de exposição, que ocorre "naturalmente" (ou seja, o pesquisador não interfere ativamente). Em contraste, nos ensaios clínicos, os pesquisadores atribuem (experimentamente) a exposição aos participantes do estudo.

Exemplo: Os investigadores pretendem avaliar se o fumo causa câncer de colo de útero. Eles recrutam 2000 mulheres com útero intacto. Os pesquisadores usam um questionário para verificar o status de fumo para todos os sujeitos do estudo e depois dividem a população de estudo em uma coorte de fumantes e outro grupo de não fumantes.

Eles observam cada coorte ao longo do tempo e comparam os riscos de incidência de câncer de colo de útero entre os dois grupos.

Os estudos de coorte geralmente se concentram na incidência de casos da doença que ocorrem durante o seguimento. Para atingir esse objetivo, os pesquisadores geralmente excluem indivíduos que têm a doença prevalente no início de um estudo de coorte (no nosso exemplo, quem já tivesse câncer de colo uterino seria excluída). A avaliação dos resultados da incidência da doença ajuda a estabelecer que a exposição de interesse precede o desfecho (doença) e, portanto, pode representar uma causa da doença.

Nos estudos de coorte, os pesquisadores observam a exposição de interesse. Como resultado, indivíduos expostos e não expostos podem variar em função de outras características. No nosso exemplo, por exemplo, pacientes que fumam podem ser mais propensas a serem portadoras de HPV que sabidamente é fator de risco para câncer de colo. O conceito de que fatores outros que não a exposição podem influenciar os resultados do estudo é chamado de fator de confusão ou de confundimento.

Apuração dos dados do estudo:

A partir do momentoem que os investigadores decidiram sobre as variáveis e desfechos específicos para o estudo, eles devem usar os métodos mais acurados possíveis para medir estas características e disponibilizando-os para todos os participantes. Considerações importantes na medição dos dados do estudo são a validade das medições, tempo entre as medições e a disponibilidade de medidas uniformes para a população em estudo.

Validade das medições:

A validade de uma medição refere-se a quão perto os dados medidos representam os dados verdadeiros. Ela deve ser a mais próxima da realidade possível.

Tempo entre as medições:

O tempo certo entre as medições da exposição e do desfecho dependerá do conhecimento prévio sobre o desfecho. Em alguns casos, os pesquisadores podem estar interessados na associação entre a exposição recente e doença, particularmente se houver a preocupação de que a exposição pode mudar durante o estudo. Por exemplo, medicamentos antiinflamatórios não-esteróides(AINH) podem causar rápida constrição das artérias renais, levando a um aumento do risco de lesão renal aguda. Investigadores que estudam a relação entre AINH e uso de medicamentos e lesão renal aguda podem concentrar seus esforços em obter uma estimativa válida de uso recente de AINH em relação à ocorrência de lesão renal aguda. A verificação do uso de medicação recente pode ser obtida por frequência de atualização de status de cada participante durante o estudo. Há outros exemplos em que a associação de interesse é a relação entre a exposição a longo prazo e a doença. Por exemplo, o tabagismo pode causar danos a um transplante de rim por gradativo espessamento das camadas íntima e média das artérias. Os investigadores neste estudo podem, portanto, escolher para avaliar em longo prazo a história de tabagismo, tais como o número de maços-anos fumados após o transplante. Os estudos de coorte não são ideais para o estudo de exposições muito recentes ou muito antigas. Exposições antigas podem mudar ao longo do tempo, obscurecendo a sua relação com o resultado de interesse. Exposições muito recentes podem confundir a relação presumida temporal entre a exposição e o desfecho.

Coleta de dados retrospectiva versus prospectiva (coorte prospectivo x coorte retrospectivo):

Os estudos de coorte podem ser classificados como concorrentes (prospectivos, clássicos) ou não concorrentes (retrospectivos). Nos estudos não concorrentes, todas as informações sobre a exposição e o desfecho já ocorreram antes do início do estudo. Nos estudos concorrentes, a exposição pode (ou não) já ter ocorrido, mas o desfecho ainda não ocorreu.

Os problemas dos estudos não concorrentes são: viés de informação e a inabilidade para controlar variáveis de confusão (falta de informação). Os termos prospectivo e retrospectivo geralmente se referem a quando os dados do estudo foram coletados em relação ao investigador. Um estudo prospectivo envolve a coleta de novos dados, muitas vezes, com o propósito de abordar uma questão específica. A distinção entre os estudos retrospectivos e prospectivos é essencialmente descritiva, que não traz geralmente impacto no plano de análise ou nos resultados do estudo, além dos já citados.

Uma grande vantagem dos estudos de coorte é a capacidade de avaliar múltiplos desfechos. Os pesquisadores das coortes em estudo são livres para estudar mais de um desfecho, desde que os sujeitos em estudo estejam livres de cada desfecho de interesse quando o estudo começou. Como exemplo, num estudo que avaliou a relação entre transplante de rim e fumo, os investigadores puderam também estudar se o fumo foi associado com o desenvolvimento de câncer nos rins ou na bexiga.

Um dos maiores estudos de coorte já conduzido foi o Nurses Health Study, que recrutou 127 mil enfermeiras com idades entre 30 e 55anos. Avaliou entre as enfermeiras, por meio de questionários enviados a cada dois anos, diversas variáveis tais como: condições de saúde, a prescrição e uso de medicação sem receita, os hábitos sociais, hábitos alimentares e físicos, entre outros. Este projeto de estudo de coorte aberta permitiu a criação de múltiplos estudos de coorte que avaliaram fatores de risco para uma ampla gama de doenças, incluindo: câncer, doenças cardíacas e fraturas, entre diversos outros desfechos. Esses estudos têm a capacidade de discernir a relação temporal entre exposição e desfecho

Ao contrário dos estudos transversais, estudos de coorte podem revelar relações temporais entre a exposição eo desfecho, desde que uma quantidade razoável de tempo tenha decorrido entre a medição da exposição e a ocorrência do resultado. A existência de uma relação temporal reforça a evidência para a exposição ser uma causa possível da doença. Note-se que estabelecer uma relação temporal entre exposição e desfecho é inerente ao desenho do estudo e não podem ser resolvido por qualquer metodologia estatística.

Desvantagens dos estudos de coorte:

a) Os estudos de coorte são estudos observacionais, e portanto estão sujeitos a fatores de confusão. Ou seja, outros fatores que estão relacionados com a exposição de interesse podem explicar algumas ou todas as associações que são observadas.

b) Incapacidade para examinar doenças que são raras ou que têm uma longa latência. Os estudos de coorte podem ser ineficientes se o desfecho é raro ou a doença tem um longo período de latência.

Exemplo 1: Investigadores querem investigar se uso de talco na infância aumenta o risco de câncer de ovário na vida adulta. Usando uma coorte, a abordagem do estudo poderia ser a de recrutar coortes de crianças com e sem uso de talco e seguir estes grupos para o desenvolvimento posterior do câncer de ovário. No entanto, muitos anos de follow-up provavelmente seriam necessários para o desenvolvimento do câncer até aidade adulta.

Neste exemplo, o longo período de latência entre a exposição e o desfecho faria esse estudo muito caro e logisticamente difícil.

Exemplo 2: Os investigadores pretendem investigar se a dormir de bruços é uma causa potencial da síndrome da morte súbita infantil (SMSI) em bebês.

Usando uma abordagem de estudo de coorte, eles poderiam identificar uma coorte de crianças que dormem em decúbito ventral e uma coorte de crianças que dormem em posição supina e, em seguida, comparar os riscos de SMSI entre as coortes. No entanto, a SMSI é relativamente rara, necessitando do recrutamento de milhares de recém-nascidos para avaliar suficientes casos de SMSI para tirar conclusões significativas. Nesse caso, um estudo de caso-controle seria mais adequado. É possível superar as limitações do estudo de coorte em doenças raras e de

grande latência usando fontes de dados que facilitem o estudo de grandes populações.

Estudos de coorte para avaliação do uso de medicações:

Os estudos de coorte podem ser uma ferramenta importante para estudar os riscos e benefícios de determinada medicação. Estes estudos podem fornecer informações específicas sobre os medicamentos que podem não serem obtidas a partir de ensaios clínicos. Em primeiro lugar, estudos de coorte podem avaliar os riscos e benefícios dos medicamentos entre populações que tendem a ser excluídas dos ensaios randomizados tais como, por exemplo: pacientes com deficiências físicas e mentais, pessoas com insuficiência renal avançada, ou aqueles com doença hepática. Em segundo lugar, estudos de coorte podem avaliar desfechos clínicos e colaterais indesejados dos medicamentos aprovados pela identificação de coortes muito grandes de usuários de medicamentos a partir de dados dos sistemas automatizados de farmácias. A principal limitação dos estudos observacionais de uso de medicamentos é a dificuldade em separar o efeito de uma medicação a partir das características básicas das pessoas. Por exemplo, estudos observacionais sobre terapia hormonal (TH) mostraram que mulheres que usaram a TH tinham baixos riscos de eventos cardiovasculares em comparação com mulheres que não usaram. Ensaios clínicos não corroboraram esses resultados mostrando, ao contrário, um maior risco de eventos cardiovasculares em usuárias de TH.

A segunda desvantagem de estudos de farmacoepidemiologia é a sua tendência para avaliar usuários de medicação crónica, em vez de novos usuários. Apesar de suas limitações, os estudos de farmacoepidemiologia continuam a ser uma importante ferramenta para avaliar os medicamentos que são usados na prática clínica.

Proporção de incidência versus taxa de incidência:

Os estudos de coorte geralmente envolvem duas coortes de comparação, mas podem ter apenas uma (comparação com outros grupos informais publicados ou dados históricos) ou mais de duas (por exemplo, diferentes grupos de níveis séricos de determinado marcador sérico ou diferentes doses de um medicamento). Independentemente do número de coortes, deve-se primeiro calcular a incidência da doença em cada grupo, ou como proporção de incidência ou como taxa de incidência. Isso deve ser feito levando-se em conta o tempo em que cada participante foi seguido no estudo, dando como resultado para cada indivíduo um valor de pessoa-tempo. A falta de consideração para pessoa-tempo pode levar a um viés, que descreve uma sistemática distorção do resultado verdadeiro. Por exemplo, suponha que em determinado estudo sobre fumantes e não fumantes, os fumantes abandonam o estudo mais freqüentemente do que os não fumantes (tabagismo pode ser uma indicação de abandono) de tal forma que os fumantes são seguidos por menos tempo do que os não fumantes.Nestas condições, seria possível observar uma menor incidência de doenças entre os fumantes, simplesmente porque eles são seguidos por menos tempo. O tempo de seguimento no denominador da taxa de incidência padroniza as taxas da doença por tempo através de gerações, eliminando esse problema em potencial.

Risco Relativo:

Assim que determinamos a incidência da doença em cada coorte, podemos comparar essas incidências. Muitos tipos de comparações são possíveis, as mais comuns são o risco relativo e o risco atribuível.

O risco relativo é definido como a incidência (proporção ou taxa) em uma coorte dividida pela incidência na coorte de referência. Por exemplo, num estudo hipotético, a taxa deincidência de insucesso do transplante de rim é 82,6 falhas por 1.000 pessoas-ano entre os fumantes e 55,3 falhas por 1.000 pessoas-ano entre os não fumantes.

Usando os não fumantes como a coorte de referência, o risco relativo seria:

$$\frac{\text{82,6 falhas por1000 pessoas-ano}}{\text{55,3 falhas por1000 pessoas-ano}}$$

RR = 1,49 (comparação entre fumantes com não fumantes)

O risco relativo também pode ser expresso utilizando os fumantes como a coorte de referência:

RR = 0,67 (comparação entre os não-fumantese fumantes)

Ambos os riscos relativos estão corretos. Você pode escolher um grupo para ser o grupo de referência. Note-se que o risco relativo não tem unidades. A interpretação do primeiro risco relativo de 1,49 seria, "transplante de rim em pacientes que fumam têm 49% mais probabilidade de desenvolver insuficiência em transplantes em relação aos não-fumantes". "Dizemos que tem " 49% mais probabilidades " porque 1,49 é 49% maior do que 1,0.

Uma interpretação do segundo risco relativo seria "não-fumantes com um transplante de rim têm 33% menos probabilidade de desenvolver insuficiência renal em relação aos fumantes. O segundo risco relativo demonstra uma associação com um menor risco de doença, pois o valor é inferior a 1,0.

Porque fumar é associado com 49% mais risco de insucesso no transplante, mas entre não fumantes, com apenas um risco 33% menor de insucesso? Em poucas palavras, porque não são os riscos relativos aditivamente simétricos para a mesma exposição? Note-se que riscos relativos, como todas as proporções, podem assumir valores variando de 0 a infinito; No entanto, 1.0 define o valor da unidade. É mais difícil obter os riscos relativos que são muito menos do que 1,0, porque eles são limitados a 0. Por esta razão, os riscos relativos que são inferiores a 1,0 indicam associações mais fortes do que as associações simétricas que são maiores do que 1,0.

Risco Atribuível (também chamado de "diferença de risco" ou "excesso de risco"):

O risco atribuível é definido como a incidência (proporção ou taxa) em uma coorte diminuída a incidência do outro grupo. Para o exemplo de transplante de rim e fumar, o risco atribuível de insucesso do transplante comparando fumantes com não fumantes seria: 82,6 falhas transplante por 1.000 pessoas-ano (fumantes) - 55,3 falhas transplante 1.000 pessoa-ano (não-fumantes) = 27,3 falhas transplante por 1.000 pessoas-ano.

Note-se que o risco atribuível, ao contrário do risco relativo, mantém as mesmas unidades que estão sendo comparadas.

Se a exposição de interesse for acausadora da doença, o risco atribuível descreve a quantidade de risco adicional ou extra que se deve à exposição. Por exemplo, se fumar realmente causa a falha de transplante renal, em seguida, a interpretação do risco atribuível para o tabagismo seria:"há risco de insuficiência renal de 27,3 transplantes renais adicionais para cada 1.000 pessoas-ano em receptores de transplantes que fumam.

ESTUDOS CASO-CONTROLE

Para introduzir o conceito do estudo de caso-controle, podemos fazer a seguinte pergunta:

O consumo de álcool aumenta a incidência de câncer de pâncreas? Estudo caso-controle publicado em 1989 mostrou aumento significativo da doença em quem consumia maiores quantidades de cerveja [1]. Considerando esta possibilidade, podemos delinear um estudo caso-controle hipotético, como exemplificado a seguir.

Primeiro vamos considerar como seria a abordagem de um estudo de coorte para este problema. Os pesquisadores conseguiram identificar uma coorte de 1.000 adultos que ingerem regularmente álcool e outra coorte de 1.000 adultos que não ingerem álcool. Após a exclusão de adultos com problemas no pâncres no início do estudo, os pesquisadores observaram cada coorte para o desenvolvimento do câncer de pâncreas (CP) durante o seguimento. Os dados obtidos com esta abordagem são apresentados na Tabela 1.

Estes dados não indicam uma diferença na incidência de câncer de pâncreas, comparando adultos que consomem álcool com aqueles que não consomem, porém, existem poucos casos de câncer de pâncreas neste estudo para chegarmos a uma conclusão significativa. Neste exemplo, o desenho do estudo de coorte é ineficiente porque o desfecho (câncer de pâncreas) ocorre com pouca freqüência.

E se o desenho do estudo de coorte fosse revertido? Se em vez de começar com coortes de expostos (os que consomem álcool) e não expostos (os que não consomem álcool), os investigadores começassem identificando adultos com e sem o desfecho de interesse, ou seja, o câncer de pâncreas?

Podemos pensar em um estudo, no qual os pesquisadores identificaram 1.300 adultos com câncer de pâncreas, numa base eltrônica de boa qualida-

Tabela 1 – *Consumo de cerveja e câncer de pâncreas: um estudo de coorte.*

	Câncer de Pâncreas		
Consumo de cerveja	**Sim**	**Não**	**Total**
Sim	5	995	1.000
Não	6	994	1.000

de, em um determinado país. Eles usaram a mesma base de dados para determinar se os casos eram consumidores habituais de álcool antes do desenvolvimento do câncer de pâncreas.

Os dados da tabela 2 demonstram uma proporção aparentemente alta (77%) de consumo de álcool nos pacientes que sofrem de câncer de pâncreas. O próximo passo seria comparar essa proporção com pacientes semelhantes (em idade,sexo, etc..), mas que não tenham CP.

Os pesquisadores usaram a mesma base de dados para obterem os dados que constam da Tabela 3. Esta tabela demonstra que a proporção de adultos sem CP e que consomem álcool (71%) é discretamente mais baixo que o grupo com CP (o que fala a favor do álcool ser fator de risco para CP).

Os resultados do estudo são mais bem apreciados através da apresentação conjunta dos dados relativos aos doentes e aos não doentes. Os dados da tabela 4 ilustram este conceito. O estudo caso-controle começa com doentes e indivíduos não doentes e, em seguida, verifica os seus status de exposição prévio ao desenvolvimento da doença. Estudos caso-controle realizados corretamente podem ser usados para sugerir relações causais importantes.

Tabela 2 – *Consumo de álcool entre os 1300 pacientes com CP.*

	Consumo de álcool	
Sim	1000	(77%)
Não	300	(23%)
Total	1300	

Tabela 3 – *Consumo de álcool entre os 4500 adultos sem CP.*

	Consumo de álcool	
Sim	3200	(71%)
Não	1300	(29%)
Total	4500	

Estudos Caso-Controle

O primeiro passo para a realização de um bem sucedido estudo caso-controle é a seleção cuidadosa dos casos e dos controles.

SELEÇÃO DOS CASOS

A. Especificar bem a doença em questão

Uma definição bem específica da doença é desejada em estudos caso-controle para garantir que a doença em questão está realmente presente entre os indivíduos que estão sendo definidos como casos. Esta estratégia pode exigir a exclusão de indivíduos com formas mais leves de uma determinada doença (ou incluí-los e melhorar a precisão diagnóstica), a fim de se concentrar em casos mais avançados, que podem ser diagnosticados com maior segurança. Em contrapartida, é geralmente menos importante dedicar recursos extras para confirmar que os indivíduos do grupo controle são verdadeiramente livres da doença em questão. Os estudos caso-controle geralmente investigam doenças raras (de baixa incidência, difíceis de serem estudadas em uma coorte), pouco prováveis de estarem presentes nos indivíduos selecionados aleatoriamente para o grupo controle.

B. Selecionar casos incidentes

Normalmente, o objetivo dos estudos caso-controle é estudar o desenvolvimento da doença; portanto, casos incidentes (novos) da doença são geralmente preferidos do que os casos crônicos, de longa duração. Uma razão para focar nos casos incidentes é estabelecer se a exposição de interesse (p.ex., consumo de álcool) esteve claramente presente antes da ocorrência da doença.

Por exemplo, a seleção de adultos com CP de longa data pode dificultar a comprovação de con-

Tabela 4 – *Consumo de álcool e câncer de pâncreas: estudo caso-controle.*

Consumo de álcool prévio	Câncer de Pâncreas		Total
	Sim (N=1300)	Não (N=4500)	
Sim	1000 (77%)	3200 (71%)	4.200
Não	300 (23%)	1300 (29%)	1.60

sumo de álcool antes do desenvolvimento da doença (p.ex., pode ter começado a beber depois que soube da doença há alguns anos e não antes – mais difícil de diferenciar com o passar do tempo). Uma segunda razão para a escolha dos casos incidentes é que a alternativa, a seleção de casos crônicos, pode atrapalhar o estudo da etiologia da doença caso esta interfira na sobrevida do indivíduo. Para ilustrar este conceito, considere um estudo caso-controle, que avalia se os marcadores séricos do estresse oxidativo estão relacionados com o acidente vascular cerebral (AVC). Os investigadores começam pela identificação de indivíduos com AVC (casos) e aqueles sem AVC (controles) e, em seguida, medem os marcadores do estresse oxidativo em amostras de soro que foram coletadas há 10 anos. Se os pesquisadores selecionassem como casos os indivíduos com AVC crônico, eles estariam estudando os "sobreviventes do AVC", cuja sobrevivência poderia estar relacionada com certas características saudáveis, incluindo menores níveis de marcadores séricos do estresse oxidativo. O resultado poderia ser uma associação negativa artificial (quanto maiores os níveis dos marcadores, menores as chances de AVC) entre os marcadores séricos do estresse oxidativo e o AVC.

SELEÇÃO DOS CONTROLES

A. Selecionar controles da mesma base populacional dos casos

Os estudos caso-controle comparam a freqüência da exposição (p.ex., consumo de álcool) entre os indivíduos que tem uma doença e os indivíduos que não tem a doença. A interpretação dos resultados de um estudo caso-controle depende do pressuposto de que o grupo controle foi obtido de uma população adequada para estimar a freqüência da exposição. O objetivo geral é a obtenção de controles que derivam da mesma base da população que os casos. No exemplo do estudo do CP, os casos do estudo poderiam ter sido selecionados a partir do sistema nacional de saúde da Suécia, onde o banco de dados tem boa qualidade e a ingestão de álcool é relativamente alta. Se os investigadores, em vez de selecionarem o grupo controle da Suécia, selecionassem os controles de um país diferente, onde a ingesta de álcool é menos comum (p.ex, países mulçumanos), teriam observado uma maior proporção de consumo de álcool entre os casos (da Suécia, que na média ingerem mais álcool), levando à conclusão falsa de que a ingesta de álcool é mais comum entre os portadores de CP.

B. Os controles devem ter a mesma oportunidade de serem selecionados como casos se, ao invés de saudáveis, fossem ou se tornasssem doentes

No estudo do CP, os controles tiveram a mesma oportunidade de serem diagnosticados como casos porque faziam parte do mesmo sistema de saúde que capturou os doentes, utilizando códigos de diagnóstico. Um método para assegurar que os casos e os controles derivam da mesma população subjacente e que vão ter a mesma oportunidade de serem diagnosticados com uma doença é fazer um estudo caso-controle aninhado. Este desenho de estudo seleciona os casos e controles a partir de um estudo de coorte maior. Por exemplo, o Cardiovascular Health Study (CHS) recrutou 5.800 idosos a partir de quatro comunidades e obteve avaliação sorológica da função renal entre todos os participantes[2]. Um estudo caso-controle aninhado no CHS pode facilmente identificar os casos com disfunção renal e controles com função renal normal, baseados em dados de laboratório que foram obtidos usando métodos idênticos. Os investigadores poderiam então tentar estimar a freqüência do uso de determinado anti-inflamatório (que pudesse prejuducar os rins) entre os casos e os controles usando dados previamente coletados sobre a prescrição médica.

C. Pareamento

Os estudos de caso-controle muitas vezes usam o pareamento para aumentar o grau de semelhança entre os casos e os controles. No estudo do CP, um exemplo de pareamento seria primeiro escolher um indivíduo com CP e, em seguida, identificar um controle que não tem CP, mas que tem a mesma idade e sexo do referido caso. Utilizando técnicas analíticas apropriadas, o pareamento pode reduzir a possibilidade de que outros fatores atrapalhem a associação entre a exposição e o desfecho (denominado confundimento; p.ex, no caso do CP, o fumo poderia aumentar a chance de CP e quem ingere álcool normalmente fuma mais; ou seja, o fator de risco para CP em quem ingere álcool seria, na verdade, o tabagismo, mais prevalente em quem bebe).

D. Número de controles

Em um estudo caso-controle, a doença de interesse é geralmente rara, logo, encontrar casos é muitas vezes o passo limitante do processo. Não há regras específicas sobre o número de controles que

são necessários em cada estudo, no entanto, mais controles geralmente fornecem uma estimativa mais precisa da freqüência de exposição no grupo controle e podem aumentar o poder de estudo (a capacidade de detectar uma associação se ela está realmente presente). Os recursos financeiros normalmente determinam o número de controles que podem ser selecionados por cada caso. Há um aumento acentuado do poder do estudo quando mais controles são adicionados, até atingir cerca de três a quatro controles por cada caso, ponto a partir do qual a adição de mais controles tem pouco efeito sobre o poder do estudo.

VANTAGENS DOS ESTUDOS CASO-CONTROLE

A. Estudos caso-controle podem ser ideais para o estudo de doenças raras ou com longo período de latência

Os estudos de coorte e ensaios clínicos randomizados podem ser difíceis de executar quando o desfecho de interesse é raro ou o período de latência entre a exposição eo desfecho é longo (p.ex., pode levar anos entre a ingesta de álcool e CP).

Os estudos de caso-controle podem ser úteis para estudar os processos em que o período de tempo compreendido entre a exposição e o desenvolvimento da doença é particularmente longo e se os dados anteriores sobre a exposição estão disponíveis ou podem ser facilmente obtidos. Por exemplo, pode demorar anos para que certos fatores dietéticos, como o óleo de peixe, possam produzir benefícios cardiovasculares. Um estudo caso-controle poderia identificar indivíduos com e sem doença coronária cardíaca e depois questioná-los quanto à freqüência e quantidade de consumo prévio de óleo de peixe (obviamente controlando para fatores de confusão).

B. Estudos de casos e controles permitem o estudo de múltiplas exposições

Os estudos de coorte identificam indivíduos com base em seu status de exposição e, subsequentemente, seguem as coortes para observar o desfecho de interesse. Em contraste, estudos caso-controle identificam indivíduos com base em seu status de doença, permitindo o estudo de várias exposições dentro de um grupo pré-definido de casos e de controles. Por exemplo, uma vez que casos de CP e controles sem CP são identificado, os investigadores do estudo poderiam explorar outros fatores de risco para CP.

DESVANTAGENS DOS ESTUDOS CASO-CONTROLE

A. Desenho de estudo observacional

Como em estudos de coorte, estudos caso-controle são desenhos de estudos observacionais e podem sofrer confundimento. Os casos podem diferir dos controles em outros fatores além da exposição de interesse. O confundimento ocorre quando um outro fator, que não a exposição de interesse, distorce a associação entre a exposição e o desfecho, limitando assim a inferência de que a exposição causa a doença.

B. Viés de memória

Como em estudos de coorte, estudos caso-controle podem obter os dados do estudo usando uma variedade de fontes, incluindo prontuários, questionários, entrevistas e exames laboratoriais. Como nos estudos de coorte, os estudos caso-controle buscam mensurações válidas, precisas e uniformes da exposição e do desfecho. Uma consideração importante para mensurações em estudo caso-controle é o uso de entrevistas ou questionários para verificar o status de exposição prévio, pois estes procedimentos podem levar a um tipo específico de viés conhecido como viés de memória. O viés de memória ocorre quando os casos e os controles lembram-se do seu status de exposição de forma diferente (ou diferencial). No caso do CP, os casos (com câncer de pâncreas) poderiam se lembrar de terem bebido mais álcool que o grupo saudável (por estarem doentes acabam tentando buscar com mais afinco algum culpado). A melhor solução para minizar o viés de memória em estudos caso-controle é a utilização de dados que foram colhidos de forma sistemática, antes do desenvolvimento da doença (p.ex. prontuários organizados e completos, usados em um sistema de saúde eficiente).

C. Estudos caso-controle de fornecem apenas informações sobre o risco relativo (razão de chance – odds ratio) da doença

Os estudos de coorte podem determinar a incidência da doença entre os expostos e indivíduos não expostos e então comparar esta incidência usando uma proporção (risco relativo) ou uma diferença

Tabela 5 - *Consumo de álcool e câncer de pâncreas: estudo de coorte.*

Consumo de álcool prévio	Câncer de Pâncreas		Total
	Sim (N=1300)	Não (N=4500)	
Sim	1000	150.000	151.000
Não	300	55.000	55.300
Total	1300	205.000	206.300

(risco atribuível). Os estudos caso-controle podem fornecer somente uma estimativa (aproximação) do risco relativo. Eles não podem ser utilizados para calcular risco atribuível, nem podem ser utilizados para calcular a incidência específica da doença em qualquer grupo.

ANALISE DOS DADOS EM ESTUDOS CASO-CONTROLE

A. Teoria do odds ratio (OR)

Os dados do estudo caso-controle do CP demonstraram que 77% dos adultos com CP possuiam história de ingesta de álcool e que 71% dos adultos sem CP possuiam esta mesma história. Normalmente estamos interessados na associação "qual é o risco de CP comparando adultos que ingerem álcool para aqueles que não?". Podemos estimar essa informação a partir de dados de estudos caso-controle utilizando o odds ratio (razão de chances). Para desenvolver o conceito de odds ratio, imagine que temos um financiamento ilimitado e recursos para estudar os adultos no sistema de saúde sueco. Realizamos um enorme estudo de coorte sobre consumo de álcool e CP. Dados hipotéticos são apresentados na Tabela 5.

Depois de recrutar mais de 200.000 indivíduos no estudo da coorte hipotética, podemos calcular a incidência (proporção) de CP em cada grupo:

Incidência no grupo de consumo de álcool = 1000/150.000 = 0,66%

Incidência no grupo sem consumo de álcool = 300/55.300 = 0,54%

Como estamos analisando um estudo de coorte hipotética, podemos usar a incidência (proporção) para calcular o risco relativo de CP em que ingere álcool = (0.66/0.54) = 1,22. Uma interpretação do risco relativo seria: "a ingesta de álcool está associada com um risco aumentado de 22% para câncer de pâncreas". Comparando os dados dos estudos de coorte e de caso-controle, vemos que os 4.500 controles representam apenas uma fração dos 205 mil indivíduos que não tem CP. No estudo caso-controle, os pesquisadores selecionaram 4.500 indivíduos do grupo controle baseados em seus recursos, poder do estudo e praticidade. Esta seleção "arbitrária" de 4.500 controles torna impossível calcular a verdadeira incidência de CP entre os indivíduos que estão expostos ou não à ingesta de álcool. Não podemos afirmar que a incidência de CP nos que ingeriram álcool é de 1000 / 4200 = 23,8% (ver tabela 4). Esta incidência é bem maior do que a incidência real de 0,66% e seria ainda diferente, dependendo do número de controles escolhido pelo investigador. Da mesma forma, não podemos afirmar que a incidência de CP entre os adultos que não ingerem álcool é de 300 / 1600 = 18,7%, pela

Table 6

Consumo de álcool prévio	Câncer de Pâncreas		Total
	Sim (N=1300)	Não (N=4500)	
Sim	1000 (77%)	3200 (71%)	4.200
Não	300 (23%)	1300 (29%)	1.600

O odds ratio é calculado como (1.000 / 3.200) / (300/1300) = 1,35.

Table 7

Consumo de álcool prévio	Câncer de Pâncreas		Total
	Sim (N=1300)	Não (N=4500)	
Sim	a. 1000	b. 3200	4.200
Não	c. 300	d. 1300	1.600

O odds ratio é calculado como (1.000 / 3.200) / (300/1300) = 1,35.

mesma razão. Como o erro ao estimar a incidência é semelhante nos expostos e não-expostos, a razão entre essas (falsas) incidências aproxima o risco relativo para a doença. Este razão de (falsas) incidências não é propriamente um risco relativo, ao invés disso tem um nome diferente, a razão de chances (odds ratio). O odds ratio é a principal medida de risco em um estudo caso-controle.

B. Cálculo prático do odds ratio (OR)

Na realidade, o odds ratio é calculado usando o número de controles (pessoas sem doença), como o denominador. Considerando os dados do estudo caso-controle do câncer de pâncreas (Tabela 6)

Interpretações igualmente corretas da razão de chances incluem:

1. A ingesta de álcool está associada com chance 35% maior de CP.

2. As chances de CP são 35% maiores entre os que ingerem álcool em comparação com aqueles que não o fazem.

3. O odds ratio (ou a razão de chances) de CP é de 1,35, comparando os que ingerem álcool com aqueles que não ingerem álcool.

Existe um método simples para o cálculo do odds ratio dos dados obtidos dos estudos de caso-controle. Primeiro, deve ser criada uma tabela de contingência com a doença/sem a doença na parte superior e expostos/não expostos do lado esquerdo. Dada essa configuração, as células da tabela são referidas como a, b, c, d, conforme mostrado na tabela acima (Tabela 7). O odds ratio é calculado a partir desta tabela como (a x d) / (b x c).

Note que não foi feito nenhum ajuste para outros fatores neste estudo, tais como idade, raça ou sexo. Como consequência, esta razão de chances é também chamado de "odds ratio "bruto", ou "odds ratio não ajustado".

C. Odds ratio e Risco relativo

Usando a abordagem do estudo de coorte, verificou-se que o risco relativo (RR) do CP, comparando quem ingere álcool com quem não o faz, foi de 1,22. Usando a abordagem de caso-controle, observou-se que o odds ratio do CP, comparando quem ingere álcool com quem não o faz, foi de 1,35. Essas estimativas são semelhantes, mas não exatamente a mesma. O principal fator que determina a concordância entre o risco relativo e a razão de chances é a raridade do desfecho em questão. Quanto menor a prevalência da doença na população, maior a concordância entre o OR e o RR No exemplo da ingesta de álcool, o CP é relativamente raro na população, pois há apenas 1.300 casos entre 206.300 indivíduos (prevalência = 0,63%). Não existe um valor de corte específico para definir o "raro", mas geralmente estudos de caso-controle com a prevalência da doença <5% irão fornecer um odds ratio que se aproxima bastante do risco relativo.

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Endereço para correspondência:
MARCO AURELIO PINHO DE OLIVEIRA
Rua Coelho Neto, 55 / 201
Laranjeiras - Rio de Janeiro - RJ
Tel.: (21) 9987-5843
E-mail: maurelio@infolink.com.br

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Original Article

Virtual Reality Environments in Surgical Training – Introducing the Pre, Trans and Postoperative Virtual Environment (OPVIR)

Ambientes de Realidade Virtual Aplicados ao Ensino da Cirurgia – Apresentação do Ambiente Virtual Pré-, Trans- e Pós-cirúrgico (OPVIR)

ROSILENE JARA REIS, PHD; AMARILIO VIEIRA DE MACEDO NETO, PHD; MÁRCIO SARROGLIA PINHO, PHD; PATRICIA ALEJANDRA BEHAR, PHD; MARIA ISABEL EDELWEISS, PHD

Graduate Program in Medicine: Surgery and School of Education, Universidade Federal do Rio Grande do Sul (UFRGS), Brazil. Graduate Program in Computer Science, Pontifícia Universidade Católica do Rio Grande do Sul (PUC-RS), Brazil.

ABSTRACT

Objectives: To briefly describe virtual reality simulators used as a tool in the teaching of ungraduate medical students and introduce OPVIR, the pre, trans and postoperative virtual environment developed by this group. Research report: In virtual reality systems used for the teaching and training of surgical principles, or any other invasive procedure in which students are expected to actively participate, the more closely the virtual model and reality resemble each other, the more intense the training experience. OPVIR is a virtual reality pretraining education tool for the teaching of basic surgical principles in medical school. The system requires students to perform a wide range of tasks, from choosing the right size gown, positioning the operating team around the surgical table, choosing instruments and starting a thoracotomy to completing a pathology requisition form. Preliminary results: In a preliminary evaluation of OPVIR, 15 medical students rated the overall virtual experience as satisfactory or highly satisfactory (scores 7 to 9 on a 10-point scale). Discussion: Our preliminary results suggest that OPVIR is useful as a pretraining education tool for medical students who have never been in contact with a surgical unit. Virtual reality systems, once integrated with other curricula and teacher support, may be a solution for medical education programs.

Key words: surgical instruction; medical students; virtual reality systems.

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INTRODUCTION

Traditional methods of teaching surgical skills used in medical schools worldwide are giving way to new information technologies; one of the most important of these new technologies is virtual reality (VR). Traditional teaching strategies based on training in the operating room are dependent on hospital volume of surgical procedures and use subjective assessment. Instruction should be based on more objective, precise evaluation criteria with immediate performance feedback.

With the introduction of new teaching technologies, curriculum changes should be dynamic and adaptable to new medical demands. Based on this premise, the Accreditation Council for Graduate Medical Education (ACGME) and the American Board of Medical Specialties (ABMS) defined, during the 2001 consensus,[1] the following paradigm shifts in the teaching and training of surgical procedures in medical schools, focusing on six core competences (knowledge, patient care, interpersonal and relationship skills, professionalism, practice-based learning, and system-based practices):

- Surgical curricula should be standardized;
- Objective assessment of student performance should be conducted at the end of each level;
- Criteria based on levels of proficiency should be applied to surgery residents.

Following the same line of arguments as for standardized guidelines, the American College of Surgeons (ACS), since June of 2008, has established as mandatory the use of simulation in all surgery residency programs, aiming to establish surgery simulation centers in order to ensure high-quality services.[2]

Taking all this into consideration, the Graduate Program in Surgery at a major federal university in southern Brazil has established a new research line focused on the development of VR tools. The first task of this interdisciplinary team was to develop a simple VR tool to introduce medical students to a surgical environment: a pre, trans and postoperative virtual environment, dubbed OPVIR.[3]

Within this context, the objective of the present paper is to briefly describe VR simulators currently used in medical training and introduce OPVIR, the pre, trans and postoperative virtual environment developed by this group.

SIMULATORS USED IN MEDICAL TRAINING

Simulators — also known as human patient simulators (HPS) — may be physical models, computer-based, or hybrids.[4] Simulators based on physical models have a reasonable degree of realism. However, these models have limitations, such as the fact that they can simulate only isolated body parts, hindering a complete illusion of reality. In addition, since these are inanimate models, they do not provide any type of feedback or objective performance scores. Teaching then relies on assistance and feedback from experienced instructors (Figure 1).

Computer-based simulators are an attractive alternative, since they provide experiences that more closely resemble reality. VR, by promoting a real-time tridimensional interaction with the computer, enables some types of interaction such as manipulation and cutting of organs of the human body. Hybrid simulators combining physical models with computers, in turn, may be used for simulations that are difficult to be reproduced only in the machine, such as tissue texture and organ shape.

Regarding manipulation by the user, simulators may be either simple or complex. Simulators that focus on the precise positioning of a needle or instrument are the simplest models. Simulations are performed through a single movement, such as needle insertion for anesthetic blockade or central or peripheral vascular access. Due to this characteristic of simplicity, virtual representation closely resembles reality, and the inclusion of tactile stimuli is feasible with a high degree of fidelity. These simulators are already commercially available; one example is the Immersion Medical CathSim Vascular Access Simulator.

With a higher level of complexity, simple manipulation simulators can simulate complete minimally invasive surgical procedures. Basic tasks provided by this resource, such as manipulation of a flexible endoscope, are relatively simple and direct. Once tasks have been completed, several nuances of instrument manipulation may be practiced. Specific tasks are developed to teach each step of the procedure individually and in an incremental manner so that some tasks can only be performed if more basic ones have been mastered. Some simple manipulation simulators are commercially available, such as the paranasal sinus surgery simulator; however, these simulators are still not widely used because they are too expensive and can be run only in high-performance computers.

Unlike the simulators mentioned above, complex manipulation simulators have not yet achieved a high degree of development and commercial availability, although they have been extensively studied. These simulators are tailored to teaching complex tasks, such as suturing blood vessels, and represent such tasks visually, with force and touch feedback. All this makes these applications

Figure 1 *- Simulator based on a physical model.*

computationally extensive. Although not "photorealistic," images have a reasonable degree of realism, and the interactive realism attained is good enough to make the experience acceptable for the teaching of certain skills using both hands.

The first complex manipulation simulator, the Minimally Invasive Surgical Trainer-Virtual Reality (MIST-VR), was developed in 1997. Its use has been validated as effective in improving the performance of students who have trained with the simulator, as well as in the evaluation of psychomotor techniques between experienced and inexperienced surgeons.[5,6] It is important to highlight that MIST-VR does not simulate a surgery, but rather graphically simple tasks, such as manipulation of a sphere to be placed inside a cube. However, these tasks use the same techniques employed in an actual surgery.

Another example of a complex manipulation simulator recently developed is the anastomosis simulator, which simulates the suturing of tubular structures. (Figure 2).[6]

BERKLEY and cols.[7] presented a suturing simulator that may be classified as complex manipulation. This model simulates, with reasonable realism, tactile feedback and deformation through finite element modeling: an accurate methodology for the design and testing of prototypes widely used in the industry. According to the authors, the use of these elements enables a realistic simulation of tactile feedback and real-time deformation of tissues. At the current stage, tactile feedback is obtained using a Phantom. Suture knots, however, are not tied by the user, but rather by pressing a key (Figure 3).

The last type of simulator used in medical training permits the student to perform an integrated procedure involving several different tasks, such as cutting, dissection, and anastomosis, combined in a complete surgical procedure. Different tissues, organs, and surgical instruments add to the complexity of the simulation environment. Although these simulators do not generated high-quality images, the interaction is realistic and provides an opportunity to practice a complete procedure. These simulators may be mannequin-based, computer-based, or hybrid. An example of an integrated procedure hybrid simulator is the knee arthroscopy simulator.[8] This simulator provides a detailed representation of the internal anatomical structure of the knee joint, and displays several different instruments used to perform various procedures.

Another application of simulators includes surgical planning, in which experienced professionals can simulate a procedure and evaluate the consequences of their decisions in a safe environment. McCLOY and STONE[9] stated that VR technologies enable the procedure to be performed and results to be analyzed before the surgery is carried out. Thus, surgical approaches can be practiced and optimized, increasing the chances of success. In order to accomplish the surgical planning, it is necessary that actual images of the organs to be operated be used in the simulators. An example of a surgical planning system is the hepatectomy simulator developed by BENES and cols.[10] for the planning of liver surgery (Figure 4).

PRE, TRANS AND POSTOPERATIVE VIRTUAL ENVIRONMENT – OPVIR

OPVIR is a virtual environment system developed to introduce medical students to operating

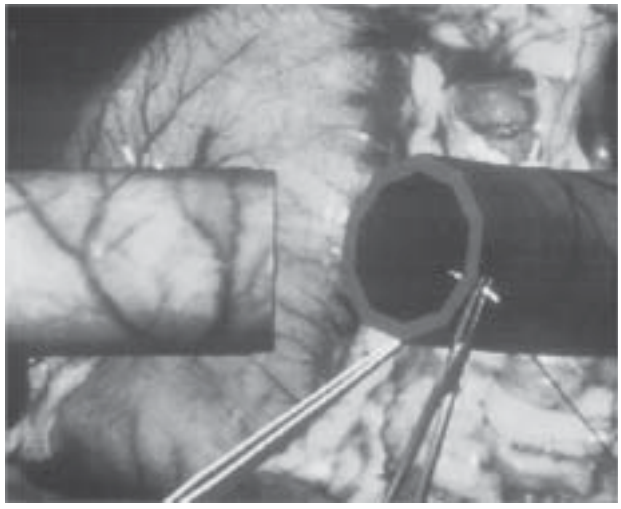


Figure 2 *- Anastomosis simulator.*

Figure 3 *- Images of a suturing simulator.*

routines. During a 40-minute immersion, students navigate and interact in this tridimensional synthetic environment by performing tasks covered in the Basic Surgical Techniques course. The system requires students to perform a wide range of tasks, from choosing the right size gown, positioning the operating team around the surgical table, choosing instruments and starting a thoracotomy to completing a anatomic pathology requisition form. The tasks were designed so that they could be easily performed. As the virtual sequence proceeds, the student receives guidance in the form of tips. When all the steps are completed, a report is generated which informs the score (correct or incorrect choices) and the time required to complete the sequence. Surgical instruments are positioned using data input devices such as a mouse, keyboard or trackers.

Table 1 describes the main scenarios featured in OPVIR.

Preliminary assessment

Fifteen medical students (age ranging from 21 to 24 years) without previous surgical experience, who had never been exposed to a virtual environment but used a personal computer (PC) regularly tested the system and filled out a 17-question assessment questionnaire focusing on system usability. All students signed an informed consent form and were interviewed concerning demographic attributes (age, gender and others).

After completing the questionnaire, students were asked to rate the program from 0 to 10 (subjective assessment) and to comment. Separately, a group of 12 professionals, including five physicians, five computer scientists and two educators were asked to try the system and then rate it.

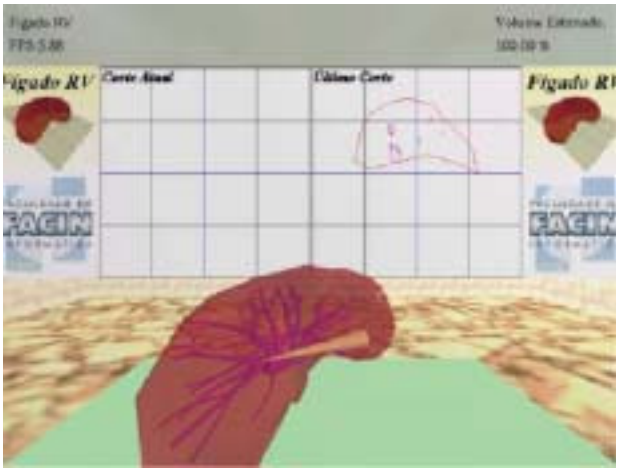


Figure 4 *- Planning environment for liver surgery.*

PRELIMINARY RESULTS

The answers provided by 15 students are summarized in Table 2.

The overall subjective scores assigned to the system by the students (from 0 to 10) were 7 (one student), 8 (four students) and 9 (ten students). Suggestions for improvement referred to more guidance (six students), improving texts and legends (five students), and more emphatic voiceovers (two students). The reasons for approval were: you learn while you play (one student); different from traditional methods (four); easy to learn (two); makes you curious (six); grabs attention (one); diversity of resources (one).

The overall subjective scores given to the OPVIR system by the 12 professionals were 9 or 10 by the five physicians; 8, 9 or 10 by the five computer analysts; and 8 by the two educators. Therefore, the subjective score assigned to the software by the professionals was similar (e" 8).

DISCUSSION

There seems to be a consensus in the literature that computer-based tools and VR systems are useful for medical training, especially in surgery. As pointed out by GALLAGHER and col.,[11] the acquisition of skills is best achieved if pretraining education is provided to ensure that the learner knows what needs to be done. Of the eight steps proposed by these authors as part of a well-thought curriculum, OPVIR can cover, even if superficially, the first five.

Teaching of surgical skills represents a challenge both for teachers, who take to the operating room their experience and knowledge to deal with unexpected situations, and for inexperienced students, who are still trying to learn the basic steps of a surgical procedure. Students should not only understand cognitive problems underlying surgical procedures, but also master technical aspects, with constant training in a surgical environment. Different from other cognitive functions in medicine, surgical skills require practical experience, preferably under the supervision of an experienced surgeon.

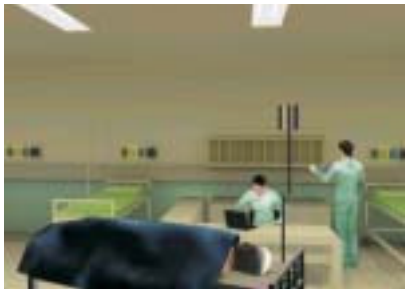
Patients undergoing a surgery want to trust their surgeon and believe that the physician can

Table 1 - *OPVIR scenarios.*

Scenario/setting	Task	Image
Introduction	Welcome and instructions	
Waiting room	Providing information to relatives	
Locker room	Choosing a gown of the right size	
Locker room	Identifying the correct locker and learning how to dress correctly	
Washroom	Learning how to wash and scrub	
Operating Room	Positioning the patient on the operating table for a thoracotomy	

Continuation ahead

Continuation of table 1

Scenario/setting	Task	Image
Operating Room	Positioning surgical team and assigning responsibilities	
Surgical instrumentation	Identifying basic surgical instruments for the thoracotomy	
Operating Room	Opening the chest, identifying anatomic landmarks and performing inspection maneuvers	
Recovery room	Transporting the patient to the recovery room	
Records	Operative report, filling out a anatomic pathology requisition form and a prescription	

perform the proposed surgery without causing the patient any injury. This poses a dilemma for both teachers and students. Surgical instructors must be judicious when allowing inexperienced students under their supervision to familiarize themselves with surgical steps (judgment skills and technical experience), they have a duty to protect their patients from inexperience errors.

Table 2 - *OPVIR Evaluation Scores (n = 15 medical students).*

	Score				
(Worst)	**0**	**1**	**2**	**3**	**4 (Best)**
Evaluation item					
Readability	2				13
Are texts clear				4	11
Are long texts adequate			5	8	2
Are icons self-explanatory			2	12	1
Quality of sounds and video				1	14
Integration of videos and audios to system and contents					15
Are scenarios pleasant					15
Are scenarios realistic					15
Are voiceovers clear					15
Was the narrator's voice pleasant		1	1	6	7
Clarity of legends and reading time				9	6
Effectiveness of navigation instructions		6			9
Clarity of theme				7	8
Relevance of topic					15
Is the system interesting			1	2	12
Are sound resources pleasant		1	1	5	8
Do sound resources contribute to realism			3	7	5
Are tasks easy to understand			2	12	1
Are tasks easy to perform			1	7	7
Degree of approval					15

Technology has become an unavoidable part of both our daily lives and medicine specifically, and it would be foolish not to prepare students to use it. Therefore, the use of simulators and virtual technologies may be a natural solution for medical education programs.

CONCLUSION

Even though a realistic representation is not considered to contribute to all training experiences,[11] we believe that virtual environments, once integrated with other curriculum contents and teacher support, may translate into a successful educational experience.

Our preliminary survey results suggest that OPVIR is viewed as a useful pretraining education tool for medical students who have never been in contact with a surgical unit. A study is currently underway to validate both the tool and its efficacy for pretraining education.

RESUMO

Objetivos: Descrever brevemente os simuladores em realidade virtual utilizados como ferramenta de ensino nos currículos de graduação em medicina e apresentar o ambiente virtual pré-, trans- e pós-cirúrgico (OPVIR) desenvolvido por este grupo. Relato da pesquisa: Nos sistemas de realidade virtual para ensino e treinamento de cirurgias, ou qualquer procedimento invasivo onde o aluno participa ativamente no meio, quanto mais próximo da realidade esse modelo virtual for, mais intensa será a experiência de aprendizagem. OPVIR é uma ferramenta de ensino pré-treinamento em realidade virtual para apresentar rotinas cirúrgicas a estudantes de medicina. O sistema requer que os estudantes realizem uma ampla variedade de tarefas, desde a escolha do tamanho correto da roupa, o posicionamento da equipe cirúrgica em volta da mesa de cirurgia, a escolha dos instrumentos e o início da toracotomia até o registro do exame anatomopatológico. Resultados preliminares: Em uma avaliação preliminar, 15 estudantes de medicina avaliaram a

experiência virtual global como satisfatória ou muito satisfatória (escores de 7 a 9 em um escala de 10 pontos). Discussão: Os resultados preliminares sugerem que o OPVIR é útil como ferramenta de ensino pré-treinamento para estudantes de medicina que nunca estiveram em um bloco cirúrgico. Os sistemas de realidade virtual, uma vez integrados a outros conteúdos curriculares e ao suporte de professores, se transformarão em uma solução para os programas de ensino médico.

Descritores: instrução cirúrgica; estudantes de medicina; sistemas virtuais.

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Address Correspondence:
ROSILENE JARA REIS
Rua Portuguesa, 259
Partenon, Porto Alegre, RS
90650-120 Brazil
E-mail: rjreis@terra.com.br
Telephone number: (+55) 51-9998 2612, (+55) 51-3012 0575
Fax: (+55) 51-3012 0575

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Original Article

Comparison of Methods for the Sterilization of Instruments Used for Laparoscopic Surgery

Estudo Comparativo de Métodos de Esterilização de Material de Uso em Cirurgias Laparoscópicas

EDUARDO CREMA[1]; EVA CLÁUDIA VENÂNCIO DE SENNE[2]; DANIELE FOSSALUSSA NESPOLO[3]; ADRIANA GONÇALVES DE OLIVEIRA[4]; CELSO JÚNIOR OLIVEIRA TELES[5]; ALEX AUGUSTO SILVA[6]

[1] Professor and Chair of Gastrointestinal Surgery, Universidade Federal do Triângulo Mineiro (UFTM), Uberaba, MG, Brazil; [2] Nurse, Nosocomial Infection Control Service (SCIH), Hospital de Clínicas, Universidade Federal do Triângulo Mineiro (UFTM), Uberaba, MG, Brazil; [3] Student, School of Medicine, Universidade Federal do Triângulo Mineiro (UFTM), Uberaba, MG, Brazil; [4] Adjunct Professor of Microbiology, Universidade Federal do Triângulo Mineiro (UFTM), Uberaba-MG, Brazil; [5] Student, School of Medicine, Universidade Federal do Triângulo Mineiro (UFTM), Uberaba, MG, Brazil; [6] Adjunct Professor of Gastrointestinal Surgery, Universidade Federal do Triângulo Mineiro (UFTM), Uberaba, MG, Brazil.

ABSTRACT

INTRODUCTION: Technological advancements have led to the development of various novelties that contribute to better health care. Among these new developments are "single-use" or disposable devices made of noble materials and designed for specific purposes in medical-surgical procedures. Various countries have adopted reuse to reduce costs. In the United States, reprocessing of single-use devices is performed by subcontractors that are regulated by the FDA (Graziano, 2006). **MATERIAL AND METHODS**: All instruments (trocars, forceps and ultrasonic scalpel) were processed at the Central Material and Sterilization Facility (CME) of HC-UFTM. After mechanical washing, the instruments underwent ultrasonic cleaning, were dried with compressed air, and sterilized with hydrogen peroxide in the Sterrad® system. Each instrument was then placed in a sterile plastic bag containing 100 mL 0.9% saline for 5 minutes. The fluid was collected obtained was sent to two different laboratories of UFTM for culture. **RESULTS**: A total of 1016 cultures were performed, including 227 on blood agar, 227 on MacConkey agar, 227 on Sabouraud agar, 227 in Löwenstein medium, and 108 in Middlebrook medium. No microbial growth was detected in any of the 1016 cultures using different media. **CONCLUSION**: The results showed that the standard technique used for the processing and sterilization of surgical instruments at the University Hospital of UFTM is effective and safe and might be used for the reprocessing of medical instruments for laparoscopic surgery.

Key words: single use, laparoscopy, tuberculous mycobacteria, reprocessing.

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INTRODUCTION

Due to technological advances, there have been various new developments that have contributed to better healthcare. One of these innovations are disposable devices classified as "single use," many manufactured with expensive materials for specific purposes in medical and surgical procedures. This is especially true in video-assisted surgeries that have adopted dissecting forceps, grabbing forceps, cutting instruments, trocars, and staplers intended to be used once. However, the technology increasingly makes these newly developed items more expensive. The products are frequently more expensive than the reimbursement provided by public and private payers. Thus individuals responsible for purchasing do not buy all the devices needed to perform the procedures [1]. This has led to a search for an alternative to moderate such outlays; the solution encountered is the reprocessing of these items, one way of controlling the cost factor while maintaining the benefit of a new product. Several countries – including Brazil – have adopted this approach to reduce the costs of utilizing technology.

Norms for the reutilization of "single use" devices have been discussed by the Ministery of Health and by the *Agência Nacional de Vigilância Sanitária* (ANVISA) [National Agency for Public Health Surveillance] since 1985 [2]. Due to the great variety of these devices in medical and hospital care, in 2001, Public Notice No. 98 was published, which established procedures for the reuse of products, generating great debate in the scientific community and among health institutions. After five years of discussion, in February 2006, ANVISA published Resolution 515, which established a list of single use materials for which reprocessing was prohibited. Among the 78 elements on the list were various instruments used in different areas of medicine, such as forceps, scissors, needles and trocars used routinely in video laparoscopic surgery. This resolution was based on safety criteria that reflected impossibility of sterilizing the instruments using methods available at the time.

Although they were not consulted and considering the use of some "single use" materials (ultrasonic scalpels, esophageal staplers), it is known that these are indispensable for performing advanced laparoscopic surgery. Furthermore, it should be noted that comparable permanent devices to substitute the disposables don't exist, since the prices were raised by multinational companies.

With regard to sterilization, the first stage is fundamental for the cleaning of surgical material, because it reduces the initial microbial burden by 99.99%, or in other words, four logarithmic cycles of the *bioburden* present on the device [3]. Therefore, whatever method used, the presence of organic material impedes the action of the physical or chemical agent during the sterilization and can impede the elimination of microorganisms capable of transmitting infections. The importance of cleaning is so great, that it appears as the first item in the regulations of the U.S. Centers for Disease Control (CDC) governing the reutilization of medical instruments. In addition, there is the question of damaging the material due to repeated use, and methods used in cleaning and sterilization that can lead to stiffening of the articulations, loss of cutting quality, among others. Still, the quality of the reprocessed device should be comparable to that offered by a new item, especially with regard to its functionality, lack of toxicity, and sterility.

The advantage of reprocessing, for healthcare institutions, was to increase the availability of materials, as well as resolve a work overload and the monitoring of the *performance* of permanent devices [4]. Reuse is a reality in this country and globally and there is no expectation that the situation will change, at least in the short to medium term in Brazil. The practice of reuse is very common, without standardization of the products and processes, and without monitoring of the impact on clinical outcomes. Given the lightness, ease of manipulation, and greater functionality of "single use" devices, surgeons prefer to use reprocessed rather than permanent devices [1]. In this context, the issue is: what is the best way to work without compromising the key qualities of the product.

Statistics from studies demonstrate that even though the practice is very common, few adverse events have been registered. The methodology of the few studies that have been carried out in this area is questionable. Although there's no evidence that reuse causes harm, there also is no proof that it doesn't cause harm. Moreover, many publications do not present any standards for products used for cleaning.

Brazil is not the only country to consider reprocessing. In the United States, reprocessing of "single use" devices is outsourced to companies regulated by the FDA [4]. In Canada, a study carried out with 421 hospitals revealed that only 20% of them had a Committee on the re-use of materials, and of these, only 30% had written protocols. In 1996, the Canadian Healthcare Association Guidelines were published with recommendations on reuse practices. In this country, critical devices are not reused (except some institutions that reuse hemodynamic/Swan-Ganz catheters). Semi-critical devices, however, are reused with greater frequency. Currently, it is the healthcare services that carry out the reprocessing, but due to the complexity of the protocols for validation, the great majority of health care services will be unable to continue this practice.

According to Graziano [4], various studies have been published in Germany about the cost-effectiveness of reuse. Although it is considered a common practice, reprocessing is subject to surveillance of the public-health officials of the country. In Australia, reuse is frequently practiced, and policies similar to those of the United States were adopted, namely that the hospitals that

reprocess are treated as re-manufacturers. England – where the greatest concern is *príons* – permits reuse in certain circumstances. Spain does not authorize reuse and hospitals that practice reuse will be held responsible for any risks experienced by the patient. Whereas Sweden permits reuse, as long as quality control standards are met, France effectively prohibits reuse.

Due to biotechnology advances in the medical and hospital equipment industry, there has been a significant replacement of permanent items with disposable items, as well as the addition of new devices. At a conference of these changes, many companies, that until the 1970s had products that were called "reusable," simply changed their labels for "single use," even though they made no changes in the composition of the product. In the United States of America, there was an increase in the number of legal actions due to this change that occurred when the manufacturer defined its product as reusable and limited the number of possible reuses. This is the way to make reprocessing safe.

As a consequence of these transformations, thousands of patients can not benefit from this important technological advance, especially those in public hospitals, whose financing is almost exclusively from the *Sistema Único de Saúde* (SUS).

The move to some permanent instruments also caused an increase in the prices of materials that are manufactured exclusively for single use and/or our reusable. At no time was any consideration given to the experience with thousands of reprocessings already carried out in a safe manner around the world. For example, we can cite the experience of the *Hospital de Clínicas* of *Universidade Federal do Triângulo Mineiro* (UFTM), which had at one point performed more than 12,000 laparoscopic procedures without ever having any outbreak of infection.

With disposable devices becoming increasingly complex and expensive, and with hospitals possessing and applying low temperature sterilization technologies, the application of its sterilization technologies to disposable materials, in order to reuse them, was a truly natural evolution. Another explanation for the reutilization is the limited availability of these devices in the marketplace, especially those that must be imported. One cannot forget, however, that there is a certain need for special care in the reprocessing of these items, so that one attains a standard of quality. The labeling of a device undergoing reutilization should contain information that permits the traceability of the material: name and location of the reprocessor, complete address, nomenclature of the device, reprocessing number, details of the reprocessing, and indications for use.

According to the manufacturer's (Johnson & Johnson) manual, the STERRAD® is a sterilizer for dental/medical/hospital materials based on hydrogen peroxide plasma technology [5]. The equipment is comprised of an aluminum circular chamber, and is totally automated and computerized and operates in 55 or 72 minute cycles. Sterilization parameters are recorded for each process in order to guarantee safety and reliability. The mechanism has a frontal opening with an optical sensor for the insertion of cassettes and barcodes for the operation of the system (10 ampoules/cassette, with two ampoules used per cycle). Each ampoule contains 1.8 ml of 58% hydrogen peroxide. The retrieval of used cassettes is performed by an internal system using a collection box. The material that is to be sterilized it is placed in the chamber. A guillotine-like door closes automatically and the chamber is subjected to a vacuum. After this, eight steps are performed: vacuum, injection, diffusion, plasma, injection, diffusion, plasma and ventilation. Each of these steps can be monitored on a liquid crystal display that, by means of an built-in printer, assure the registry of each phase of the sterilization cycle. The equipment is automatic and thus does not need human monitoring. If there are variations in the load conditions of sterilization, the system detects the failure, cancels the cycle and emitting an alarm sound/beep. In addition a report indicates the cancellation and its probable cause.

According to the information above, it is essential to carry out studies aimed at the sterilization of single-use devices that are being reprocessed, in order to assess whether there are risks or not in the reuse of these materials and which is the most efficient method for performing this procedure [6, 7, 8, 9]. Given that the reprocessing of "single use" devices in laparoscopy is a common practice, it is important to analyze the efficiency of processing methods and sterilization of materials, since these devices can serve as a source of acquisition of microorganisms by patients undergoing surgery. Therefore, standardization of the methods of sterilization is necessary, as there is no standard for this procedure in Brazil.

SPECIFIC OBJECTIVES

Verify the feasibility of reusing "single use" laparoscopic materials after reprocessing, evaluating the risk of the patient acquiring any pathogens coming from the reprocessed material. For this, cultures in *Blood agar*, *Sabouraud agar*, *MacConkey agar*, *Middlebrook* culture media and *Löwestein* media will be carried out to verify if there is bacterial or fungal growth after reprocessing employing sterilization of devices using the SterradÒ method.

MATERIALS AND METHODS

In order to describe the steps and components of the process, we first prepared a flowchart of the steps in the reprocessing of "single use" 5 and 10 mm trocars, forceps and cutting forceps used in videosurgery. The material used was: 5 trocars (two 10 mm and three 5 mm), and two laparoscopic forceps (scissors, scalpel, and endostaplers).

The pieces used were new and sterilized upon manufacture. First they were placed in sterilized plastic bags, and individually and totally immersed in 100 ml saline for 10 minutes. After this, the liquid was collected and centrifuged at 3,000 rpm for another 10 minutes. After centrifugation, the supernatant was aspirated and discarded, and the residue was seeded on culture plates that were placed in an incubator at 37.5º C with 5% CO_2.

The cultures were performed by two laboratories, the Microbiology Laboratory of *Hospital de Clínicas* of the *Universidade Federal do Triângulo Mineiro* (UFTM) and the Microbiology Research Lab of the UFTM. The media used were *Blood agar* (used to isolate non-fastidious microorganisms, for verification of hemolysis by *Streptococcus spp*. and *Staphylococcus spp*. and presumptive identification of *Haemophilus spp*.); *Sabouraud* Agar (used for the cultivation and growth of species of *Candida* and filamentous yeast, especially those associated with superficial infections); *MacConkey agar* (for the isolation of *gram* negative bacilli – enterobacteria and non-fermentors – and verification of the presence or absence of fermentation of lactose); *Middlebrook* media (for the isolation of rapidly growing mycobacteria) and *Löwestein* media (for the primary isolation of mycobacteria). Incubation times for each type of plate are: *Blood agar* 24 hours; *Sabouraud agar for* 40 days; *MacConkey agar* for 24 hours (if there was no growth, plate would be incubated for an additional 24 hours); *Middlebrook* media for 60 days; *Löwestein media* for 60 days.

Immediately after the gastrointestinal surgeries were performed, the trocars and the forceps are subjected to the same technical procedures described above, and the liquid was plated for culture.

The processing of the trocars, forceps and ultrasonic bisturis was carried out by the Material and Sterilization Center of HC-UFTM. Instruments were received immersed in sterile water, taken apart and, soon thereafter, immersed in enzymatic detergent for 2 to 5 minutes, in accordance with the recommendations of the manufacturer (with injection of the detergent into the lumen of the instrument using a syringe). The trocars and the forceps scalpel were scrubbed with special brushes for two minutes and immediately flushed with pressurized water, and then passed under compressed air for five minutes. Cannulas were sent to an ultrasonic washer, and were subsequently inspected under a magnifying glass. When they were found to be in accordance, they were dried with compressed air and then subjected to a process of sterilization with hydrogen peroxide in the STERRAD® equipment. After this process was completed, specimens were again collected for culture following the same sequence of procedures described above.

RESULTS

A total of 1016 cultures were carried out, 227 on blood agar media, 227 on *MacConkey agar*, 227 on *Sabouraud agar*, 227 on *Lowenstein* culture media, and 108 on *Middlebrook* media. Half of the samples were processed at the Central Laboratory of the *Hospital de Clínicas* of UFTM and the rest at the Microbiology Research Laboratory of UFTM. Even with various media used, and each specimen cultured at two different laboratories, in none of the 1016 cultures was the growth of microorganisms – either bacteria or tuberculous mycobacteria – detected.

CONCLUSION

Based on the material evaluated, it can be concluded that the processing and sterilization of trocars, forceps and endostaplers utilized in laparoscopic surgeries carried out at the *Universidade Federal do Triângulo Mineiro* (UFTM) are effective and safe.

RESUMO

INTRODUÇÃO: Devido ao avanço tecnológico surgiram várias novidades que vieram para dar maior assistência à saúde. Uma dessas novidades são os artigos classificados como de uso único (ou descartáveis), muitos deles construídos com materiais nobres para finalidades específicas em procedimentos médico-cirúrgicos. Vários países têm adotado medidas de reutilização para reduzir os custos. Nos Estados Unidos, o reprocessamento de artigos de uso único é realizado por empresas terceirizadas regulamentadas pelo FDA (Graziano, 2006). **MATERIAL E MÉTODOS**: Todo o material (trocáteres, pinças e bisturi ultrassônico) foi processado pela Central de Materiais e Esterilização (CME) do HC-UFTM. Após lavagem mecânica, os instrumentos foram encaminhados para lavadora ultrassônica, secagem com ar comprimido, e posteriormente submetidos à esterilização com peróxido de hidrogênio pelo aparelho STERRAD®. Em seguida, cada instrumento foi colocado em saco plástico estéril com 100 ml de soro fisiológico 0,9% durante 5 minutos. Realizou-se culturas em dois laboratórios distintos da UFTM. **RESULTADOS**: Foram realizados um total de 1016 culturas, sendo 227 culturas no meio Ágar Sangue, 227 Ágar MC Conkey, 227 Ágar Sabouraud, 227 Lowenstein e 108 Middlebrook. Em nenhuma das 1016 culturas com os diversos meios utilizados detectou-se o crescimento de microorganismos. **CONCLUSÃO**: Com base neste material pode-se concluir que o processamento e a esterilização destes instrumentos através da técnica padronizada no HC da UFTM são eficazes e seguros, e podem ser empregados no reprocessamento dos materiais de uso em cirurgias laparoscópicas.

Palavras-chaves: uso único, laparoscopia, micobactéria tuberculose, reprocessamento.

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Correspondence Address:
DR. EDUARDO CREMA
Rua Marcos Lombardi, 305
Bairro Santos Dumont
Uberaba, MG, Brazil 38050-170
E-mail: cremauftm@mednet.com.br

Brazilian Journal of Videoendoscopic Surgery

Original Article

Surgical Technique of Laparoscopic Total Hysterectomy

Técnica Cirúrgica de Histerectomia Total Laparoscópica

WILLIAM KONDO[1]; MONICA TESSMANN ZOMER[2]; ANÍBAL WOOD BRANCO[3]; LUCIANO CARNEIRO STUNITZ[4]; ALCIDES JOSÉ BRANCO FILHO[5]; SANDRO NICHELE[6]

[1.] General Surgeon and Gynecologist, Sugisawa Hospital and Medical Center and Vita Batel Hospital, Curitiba, Paraná; [2.] Gynecologist, Dona Helena Hospital, Joinville, Santa Catarina; [3.] Urologist, Vita Batel Hospital, Curitiba, Paraná; [4.] Urologist, Vita Batel Hospital, Curitiba, Paraná; [5.] General Surgeon, Vita Batel Hospital, Curitiba, Paraná ; [6.] Urologist, Vita Batel Hospital, Curitiba, Paraná.

ABSTRACT

Hysterectomy is the most common major gynecologic surgical procedure performed worldwide. Benign diseases (menstrual disorders, myomas, pelvic pain and uterine prolapse) account for more than 70% of the indications for hysterectomy. Hysterectomy has been traditionally performed by open abdominal or vaginal surgery, but recently laparoscopy has become an alternative surgical route with good outcomes. Advantages of the laparoscopic approach compared to open surgery include less intraoperative bleeding, shorter duration of hospitalization, faster convalescence, and lower rates of wound and abdominal wall infections; surgical time, however, seems to be increased. In this article we discuss some technical issues of laparoscopic total hysterectomy.

Key words: Total histerectomy. Laparoscopy. Technique.

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INTRODUCTION

Worldwide hysterectomy is the most commonly performed major gynecological surgical procedure. Benign diseases are responsible for more than 70% the indications for hysterectomy and include menstrual disorders, myomas, pelvic pain, and uterine prolapse.[1]

Hysterectomies are usually performed by laparotomy or through a vaginal approach.[2] However, since the description of the surgical technique of a completely laparoscopic hysterectomy in 1989, this minimally invasive approach has been considered an alternative path of access to the traditional techniques of hysterectomy.

Although the vaginal and laparoscopic approaches have advantages over open surgery, the latter remains the most widely used means of access for performing hysterectomies worldwide. In Denmark, 80% of the hysterectomies for benign disease between 1988 e 1998 were performed by laparotomy.[4] During the period from 1988 to 1990, close to 1.7 million were performed in the United States and 75% of these were performed through the abdominal approach.[5] In 2003, the abdominal approach was still the most common (66.1%) in the hysterectomies performed for benign disease in the United States followed by the vaginal approach (21.8%) and by laparoscopic hysterectomies (11.8%).[6] In a transverse multicenter study including 23 French university medical centers, the rates of laparotomy, vaginal hysterectomy, and laparoscopic hysterectomy were 43.4%, 47% and 9.6% respectively, in May 1996.[7] A study carried out between June and December of 2004 including 634 women who underwent hysterectomies for benign disease at twelve French university hospitals showed that there was an important reduction in the rate of laparotomies, with the surgery performed through a vaginal approach in 48.3%, via laparotomy in 24.4%, through a vaginal approach assisted by laparoscopy in 8.2%, and laparoscopically in 19.1%.[8] In Brazil, for the year 2009, 105,054 hysterectomies were performed for benign disease in the public healthcare system (Sistema Único de Saúde), with 89.9% abdominal, 10% vaginal, and only 0.1% laparoscopic.[9]

The advantages of the laparoscopic approach compared to open surgery include less intra-operative

bleeding, shorter hospital stay, a faster recuperation, and a lower rate of infections of the wound and the abdominal wall, with the tradeoff being that surgical time is longer.[10] Although various authors have demonstrated an increased rate of ureteral and bladder lesions with laparoscopic access,[10,11] miniseries published recently including 4505 women who underwent hysterectomy using different approaches (laparoscopic, vaginal and laparotomy) did not show a statistically significant difference in the rates of major complications when the three groups were compared.[12]

In this article we address the technical details of laparoscopic total hysterectomy.

TYPES OF LAPAROSCOPIC HISTERECTOMY

Various laparoscopic hysterectomy techniques have been proposed, reflecting the proportions of procedures performed by laparoscopy and vaginally. The classification of the American Association of Gynecologic Laparoscopists was published in 2000,[13] with the aim of standardizing the terminology of this procedure.

· Type 0 = Laparoscopic preparation for a vaginal hysterectomy, including the release of adhesions and/or the excision of endometriosis.

· Type 1 = Occlusion and sectioning of at least one ovarian pedicle, utero-ovarian or infundibulo-pelvic ligament, but not a uterine artery.

· Type 2 = Type 1 associated with the occlusion and sectioning of one or both of the uterine arteries.

· Type 3 = Type 2 associated with a portion (but not all) of the complex, unilateral or bilateral.

· Type 4 = Total freeing of the cardinal-uterosacral complex, unilateral or bilateral, with or without entering in the vagina. Includes laparoscopic total hysterectomy.

The laparoscopic total hysterectomy is defined as a hysterectomy performed completely by laparoscopy, including the suturing of the vaginal vault. With advances in laparoscopic techniques and expanded training in gynecologic laparoscopy, the portion of type 2 and 4 laparoscopic hysterectomies should increase.[14]

INDICATIONS FOR LAPAROSCOPIC HISTERECTOMY

The indications for laparoscopic hysterectomy are the same as those for a hysterectomy by other routes. The specific indications for laparoscopic access are those cases in which there is a contraindication to vaginal hysterectomy.[10,15] A Cochrane Collaboration systematic review encompassing 27 studies (3643 patients) compared the results of abdominal, vaginal and laparoscopic hysterectomy, and concluded that vaginal access should be preferred in relation to abdominal access, based on the best results. The authors also concluded that when a vaginal hysterectomy was not possible, a laparoscopic hysterectomy could avoid the need for an abdominal hysterectomy, but requires a longer surgical time (mean difference of 25.3 minutes).[10]

Compared with the path of vaginal access, laparoscopy permits the performance of concomitant procedures (appendectomy, adnexal surgery, excision of endometriosis) and the inspection of the peritoneal cavity in search of other disease. In 2005, the American College of Obstetricians and Gynecologists Committee Opinion listed the following indications as appropriate for the use of laparoscopic-assisted vaginal hysterectomy: lysis of adhesions, treatment of endometriosis, management of leiomyomas that make a vaginal hysterectomy more difficult, ligation of the infundibulo-pelvic ligaments to facilitate the removal of difficult ovaries, and the evaluation of the abdomino-pelvic cavity before the hysterectomy.[16]

The eVALuate study[17] compared abdominal hysterectomy (laparoscopic or laparotomic) and a vaginal hysterectomy, and observed that laparoscopy permitted a higher detection of unexpected pathologies such myomas, endometriosis, and adhesions, when compared with vaginal access (16.4% vs. 4.8%; $p < 0.01$) and when compared with an abdominal approach (22.6% vs. 12.7%; $p < 0.01$). There are no data, however, that this detection influenced the performance of additional procedures by the surgeons or would affect the long-term outcome.[17]

CONTRA-INDICATIONS

The contraindications for laparoscopic hysterectomy are the following:[14]

· Medical conditions that contraindicate the establishment and maintenance of pneumoperitoneum.

· Inexperience or inadequate training of the surgeon.

· Malignancy that could require the intact removal of the specimen or special procedures that

cannot be performed due to skill, access, or other circumstances.

· Lack of adequate instrumentation.

INTRA-OPERATIVE CONSIDERATIONS

Randomized trials have demonstrated a decrease in the infection of the surgical site with the use of prophylactic antibiotics in potentially contaminated surgeries and their use is recommended in the case of laparoscopic hysterectomy.[15] Antibiotic prophylaxis should be administered within one hour of the skin incision and should not be continued for more than 24 hours.

SURGICAL TECHNIQUE[18,19]

Positioning

The patient is positioned in dorsal decubitus, under general anesthesia, with oral tracheal intubation. The legs are positioned in 30°flexion; the arms along the body, and the buttocks extending slightly over the edge of the surgical table (Figure 1). The bladder is catheterized.

The surgeon is positioned to the left of the patient, the primary assistant on the right, and the second assistant is responsible for uterine manipulation.

Uterine Cannulation

Uterine cannulation is performed with a specific instrument: the Clermont-Ferrand type Karl Storz uterine manipulator (Figure 2).

Hysterometry is performed, the cervix is dilated to Hegar number 9, and the manipulator is inserted under direct vision into the cervix. The size of the tip to be used varies with the size of the uterus according to hysterometry.

Establishing the Pneumoperiteum

We routinely perform puncture with the Veress needle at Palmer's point (left upper quadrant, about 2 to 3cm below the left costal margin, in the medial midclavicular line) and the pneumoperitoneum is insufflated to a pressure of 12 to 14 mmHg. Before performing the puncture it is important that an orogastric catheter is passed in order to empty the stomach, avoiding inadvertent puncture of this organ.

Positioning the Trocar

Four trocars are positioned: one 10 mm umbilical trocar with a 0° optic and three 5 mm trocars, with one 2 cm medial to the right superior iliac crest, another 2 cm medial to the left anterior superior iliac crest, and a third in the midline, 8 to 10 cm below the umbilical scar (Figure 3). This last 5 mm trocar can be substituted by a 10 to 15 mm trocar during surgery for the introduction of suture needles for the suturing of the vaginal vault, a morcellator, or a laparoscopic

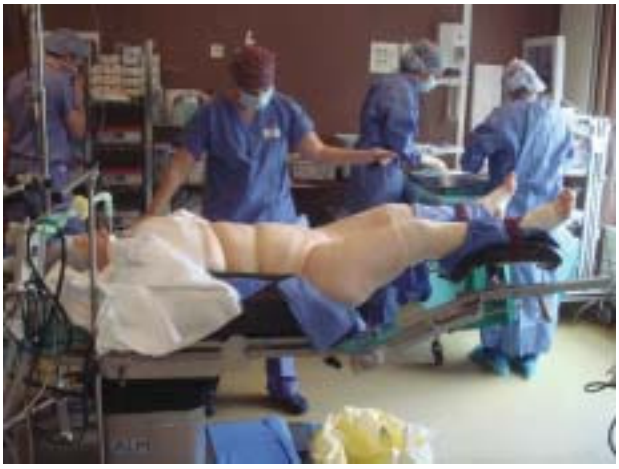

Figure 1 *- Positioning the patient for the hysterectomy.*

Figure 2 *- The Clermont-Ferrand (Karl Storz) uterine manipulator.*

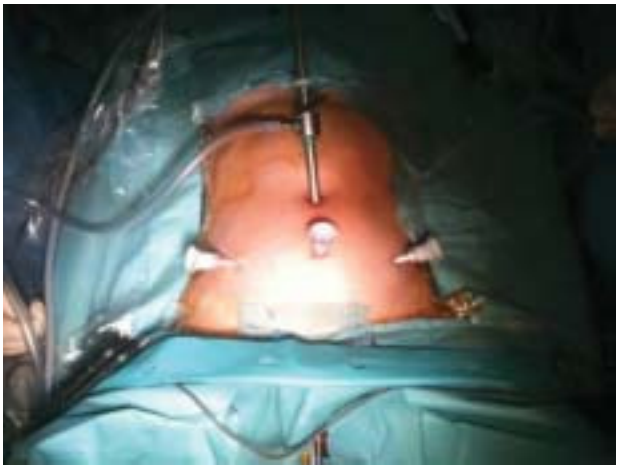

Figure 3 *- Positioning the trocars for a laparoscopic hysterectomy.*

cold scalpel (in the case of voluminous uteri that need morcellation for the removal of the vaginal route). In the case of very voluminous uteri, the trocars can be positioned more cranially.

After positioning of the first trocar, the patient is placed in Trendelemburg position. The loops of the small intestine are displaced in a cranial direction so that the promontory can be visualized.

The surgeon uses a bipolar cautery in the left hand and scissors in the right hand. The first assistant manipulates the optic with the left hand and uses the grasping forceps with the right hand.

Presentation of Round Ligaments

On the left, the freeing of adhesions between the sigmoid colon and the utero-ovarian ligament permits the correct exposure of the round ligament. The uterus is mobilized by the second assistant and is maintained cranially and anteriorly, so as to be opposite the side that will be operated. The round ligament is secured with traction by the first assistant, making possible its exposure for the start of the surgery.

Coagulation and Section of Round Ligaments

The coagulation of the round ligament is performed about 2 to 3 cm from the pelvic wall using a bipolar cautery and the section is performed with the laparoscopic scissors (Figure 4A). The coagulation of the round ligament near the uterus makes the procedure more difficult since dissection very close to the uterine body results in greater bleeding.

Opening the Anterior Leaflet of the Broad Ligament to the Vesico-Uterine Peritoneal Reflection

The uterus is placed in a horizontal orientation by the second assistant. The interior leaflet of the broad ligament is coagulated with the bipolar forceps and sectioned, from the round ligament to the vesico-uterine peritoneal reflection (Figure 4B).

Fenestration of the Broad Ligament

The capillaries of the posterior leaflet of the broad ligament are coagulated. The visualization of a blue-gray color in peritoneal leaflet indicates that there is no gastrointestinal element behind this structure. The posterior leaflet of the broad ligament is cut and the opening is enlarged using divergent traction between the bipolar forceps and the scissors of the surgeon in the anterior-posterior direction (Figures 4C and 4D). With this, the adnexa remain pedunculated and the ureter is kept out-of-the-way, since it is mobilized along with the peritoneum.

Coagulation and Section of the Infundibulo-Pelvic Ligament (Total Hysterectomy with Bilateral Adnexectomy) or of the Utero-Ovarian Ligament and the Fallopian Tubes (Inter-Adnexal Total Hysterectomy)

The first assistant should secure the adnexa and apply traction in a direction opposite to the lombo-ovarian ligament. The coagulation-sectioning of the ligament should be progressive, plane to plane (peritoneum, followed by the vessels and connective tissue) (Figures 5A and 5B). When you want to preserve the adnexa, the coagulation-section is performed proximal to the fallopian tubes and the utero-ovarian ligament (Figures 5C and 5D).

Opening the Posterior Leaflet of the Broad Ligament to the Cervix

The dissection continues on the posterior lamina of the broad ligament, avoiding inadvertent injury of the vessels of the uterine pedicle (Figure 6A). The peritoneum is pulled and dissected, coagulated and cut toward the utero-sacral ligaments. Thus the uterine pedicle is isolated and skeletonized. All steps from the coagulation-section of the round ligaments to the opening of the posterior leaflet of the broad ligament are performed in the same way on both sides.

Opening of the Vesico-Vaginal Space

The uterus should be mobilized cranially and posteriorly to expose the bottom of vesico-uterine sac. The assistant uses an atraumatic forceps to grasp the peritoneum and the bladder in the midline, applying vertical and cranial traction. The peritoneum and the adjacent connective tissue are coagulated and sectioned, thus accessing the vesico-vaginal plane. The dissection continues in a caudal direction, initially in the midline and then laterally, performing the coagulation-section of the vesico-uterine ligaments (Figure 6B). The introduction of a valve of the manipulator permits finding the plane and facilitates dissection.

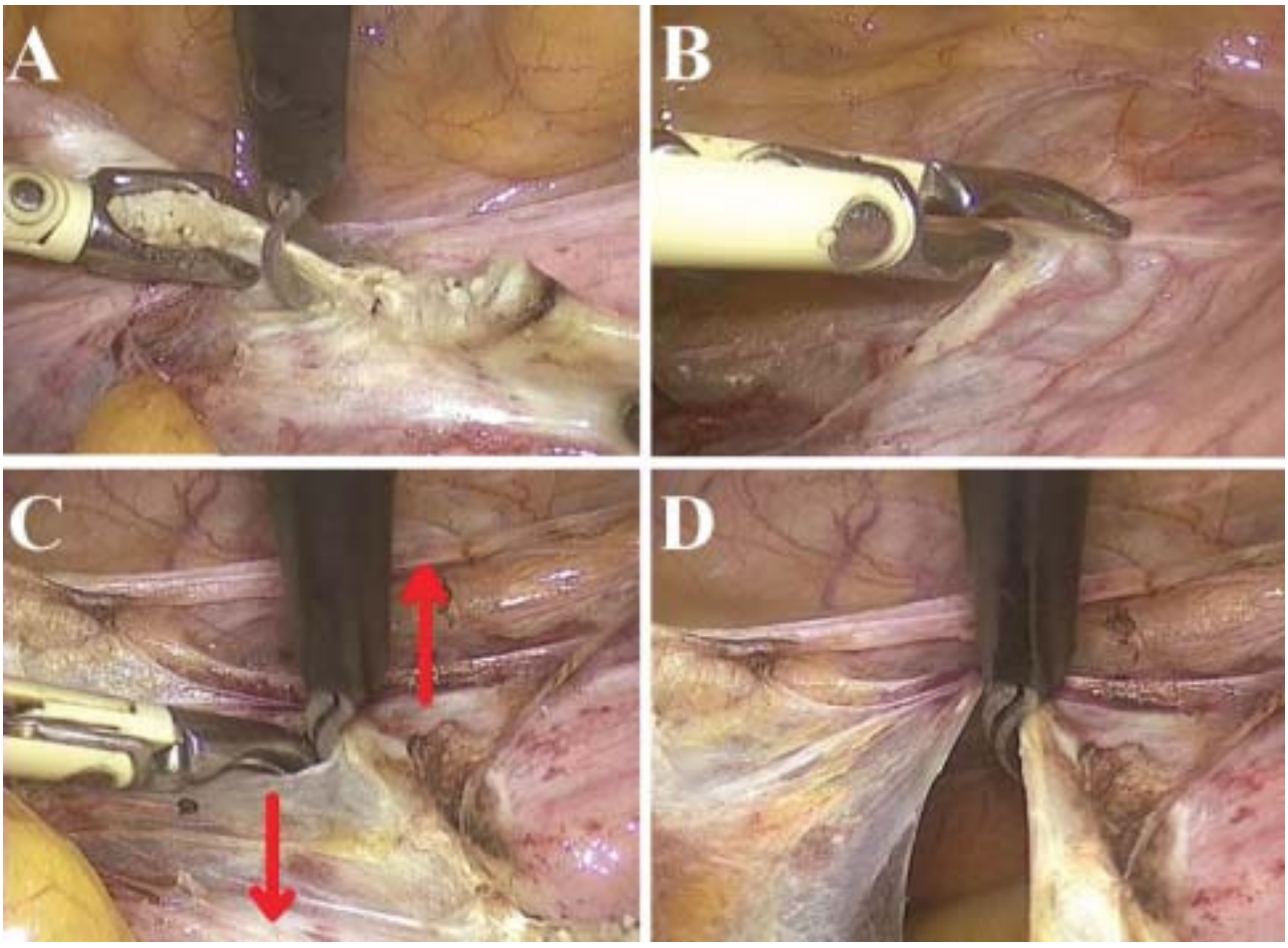

Figure 4 *- (A) Coagulation of the round ligament and section with laparoscopic scissors. (B) Opening of the anterior leaflet of the broad ligament from the round ligament to the anterior peritoneal reflection. (C and D) Fenestration of the broad ligament by divergente anterior-posterior traction of two instruments (scissors and bipolar forceps).*

Coagulation and Section of the Uterine Pedicles

The uterus is again oriented cranially and laterally by the second assistant. The first assistant applies traction to the adnexa or the round ligament cranially and laterally. The pedicles should be very well isolated permit effective bipolar regulation. The coagulation-section of the uterine pedicles, performed on the ascending segment of the uterine artery, should be carried out in a progressive manner. The bipolar forceps is introduced by the lateral trocar, on the same side as the pedicle to be coagulated (Figures 6C e 6D). During the surgical time the assistant will perform the coagulation of the uterine veins on right side.

After the coagulation of the uterine vessels, the pericervical fascia is incised at the same level as the coagulation of the uterine pedicles, in order to enter intra-fascial plane. The cervico-vaginal vessels and the insertion of the uterosacral ligament are coagulated and sectioned.

Vaginal Opening

The system to prevent loss of pneumoperitoneum is inserted into the vagina and the valve of the manipulator is pushed in a cranial direction. Monopolar section is performed across the valve starting at the anterior and median part of the vagina. It continues laterally to the left, then posteriorly. The second assistant helps by successively exposing each part of the vaginal fornix and achieves the rotation of the valve. Generally, we prefer that the surgeon handles the valve of the manipulator. The surgeon grasps the manipulator with the left hand and holds the monopolar cautery in the right hand through the suprapubic trocar. In this way one attains the perfect synchrony between the manipulator valve and monopolar cautery, avoiding thermal injury arising from the monopolar energy. The

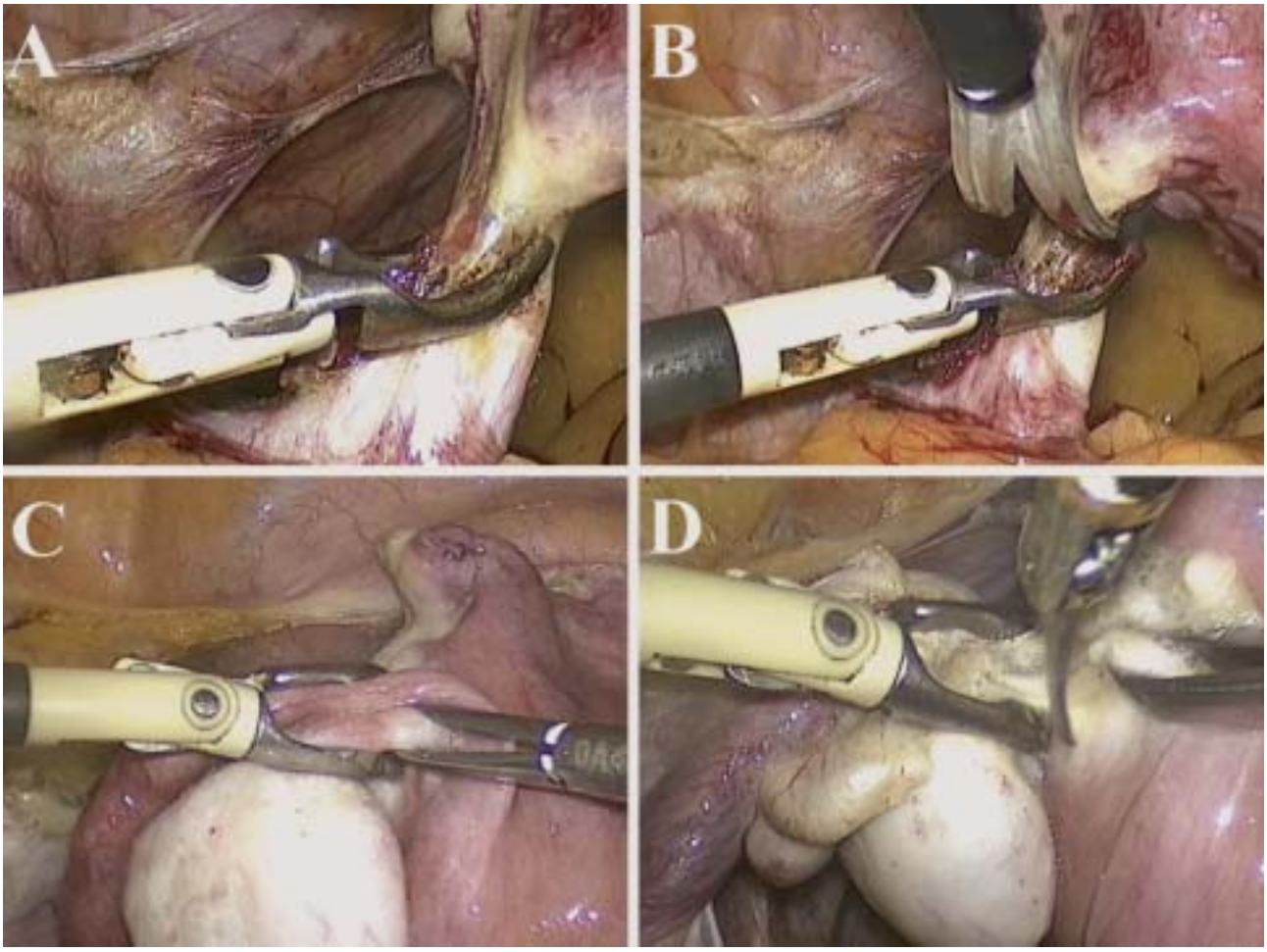

Figure 5 *- (A and B) Traction of the left adnexa by surgical assistant followed by progressive bipolar coagulation of the infundibulo-pelvis. (C and D) Coagulation and section of the left fallopian tube and of the left utero-ovarian ligament in a case of adnexal preservation.*

opening of the vault proceeds towards the right side and ends posteriorly (Figures 7A and 7B). The first assistant suctions the cautery smoke. Occasionally additional hemostasis with a bipolar forceps is necessary.

Extraction of the Surgical Specimen

The extraction was executed by the vaginal route in the majority of cases. On some occasions uterine morcellation may be necessary, carried out laparoscopically (cold scalpel or electric morcellator) or vaginally (vaginal valves and classic cold scalpel).

Vaginal Suture

We performed the vaginal suture with three X sutures using number 0 absorbable monofilament (Polyglecaprone, Caprofyl®, Ethicon Inc.) (Figure 7C), beginning with the left angle of the vagina, proceeding to the right angle, and then to central region of the vagina.

Adnexal Pexis

In cases of laparoscopic interadnexal total hysterectomy we perform the pexis of the fallopian tubes and the ovary to the ipsilateral round ligament using sutures with polyester thread (Ethibond® 2-0, Ethicon Inc) to prevent post-operative adnexal torsion.[20]

Hemostasis is confirmed (Figure 7D). The aponeurosis of the 10 mm trocar in the midline is sutured with 0 polyglactin 910 thread (Vicryl®, Ethicon Inc.). The pneumoperitoneum is disinsufflated and the skin is sutured with inverted sutures of 3-0 absorbable monofilament (Polyglecaprone 25, Monocryl®, Ethicon Inc).

Alternatives to the Use of Bipolar Energy

There are several technical alternatives to the use of bipolar energy for total laparoscopic hysterectomy. The use of bipolar energy seems to

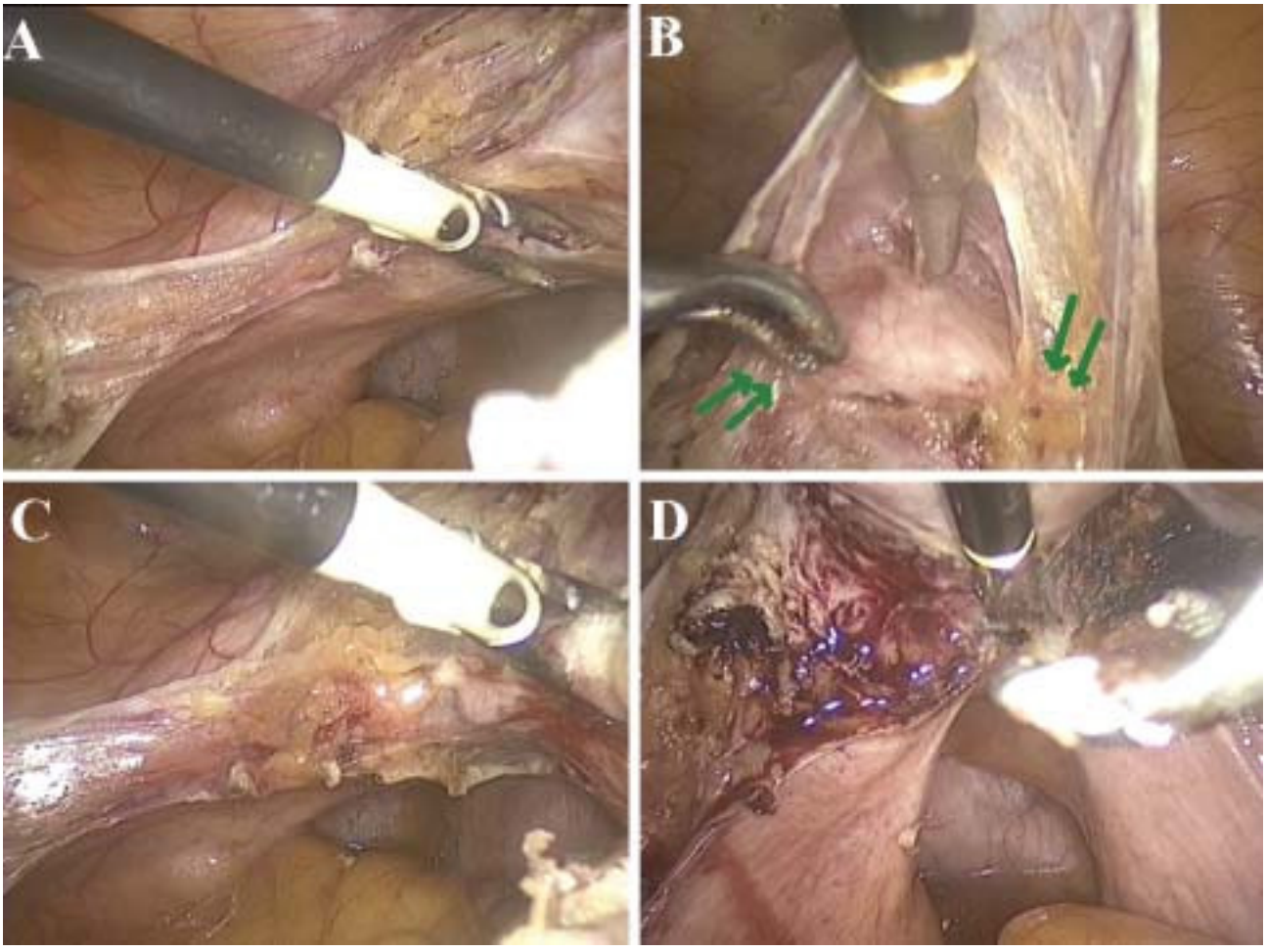

Figure 6 *- (A) Opening of the posterior leaflet of the broad ligament to the cervix. (B) Dissection of the vesico-vaginal space. The green arrows indicate the area to be coagulated (vesico-uterine ligaments). (C) Coagulation of the left uterine vessels using bipolar forceps. (D) Intra-fascial plane on the right side.*

provide a cost-effective and safe way to have control of the uterine vessels and precision during dissection and sectioning of the structures. However, the use of other disposable laparoscopic instruments can help the surgeon and shorten surgical time a bit. Options include linear cutting endostaplers (Figure 8A), the LigaSure Vessel Sealing® (Valleylab) system of vessel ligation (Figure 8B), the EnSeal® Advanced Tissue Sealing Technology tissue sealing system (Figure 8C) and the Ultracision ® harmonic scalpel (Figure 8D). Each surgeon should develop his own routine and use the available materials and technology to facilitate the surgical procedure.

POST-OPERATIVE CONSIDERATIONS

We usually remove the bladder catheter soon after the end of the surgery or a maximum of two hours after the procedure. For postoperative analgesia we prescribe IV dipyrone q 6 hours and ketoprofen q 12 hours. Additional analgesia with 3 mg of morphine every four hours can be prescribed as needed. Daily subcutaneous Enoxaparin 40mg is given for prophylaxis of deep venous thrombosis and thromboembolism. The patient is kept NPO for six hours after the procedure; when she no longer has nausea or vomiting she may receive a liquid diet. The vast majority of patients are discharged 24 hours after surgery.

COMPLICATIONS

Hysterectomy is a safe procedure, with a low rate of mortality, estimated at 0.12 to 0.34 per 1000 surgeries.[15]

The complications directly related to laparoscopic access include those related to the positioning of the Veress needle and the trocars

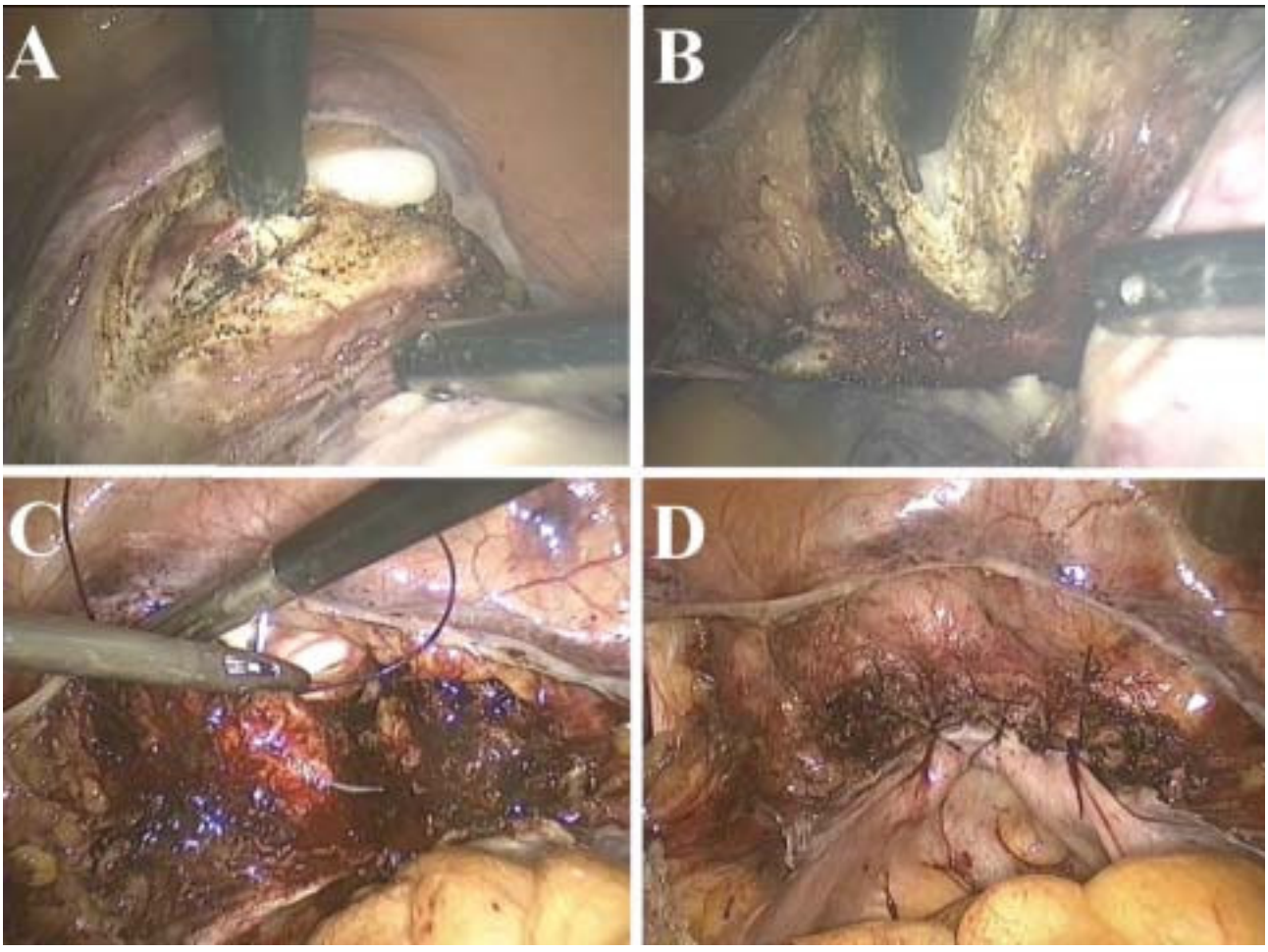

Figure 7 *- (A and B) Opening of vaginal vault with monopolar cautery. (C) Closure of the vaginal vault. The assistant places traction on the vagina three X stitches/sutures using 0 caprofil. The figure illustrates the suture in left angle of the vagina, which should include the left utero-sacro ligament. (D) Final view of the vaginal vault after the inspection for hemostasis.*

(bleeding, intestinal lesion), those related to pneumoperitoneum, hernia in the orifice of the trocars, and the need to convert to open surgery. Other complications are related to the surgical procedure itself and are basically the same, regardless of the route of access used for the hysterectomy.

The VALUE (Vaginal Abdominal Laparoscopic Uterine Excision) study evaluated the severe complications in 37,295 women who underwent abdominal hysterectomy (64%), vaginal hysterectomy (30%) and laparoscopic guided vaginal hysterectomy (3%).[21] The global rate of severe complications was 3.5%, including visceral lesions, hemorrhage, death, acute myocardial infarction, thromboembolic events, cerebrovascular accidents, and organ failure. The risk was greater in patients who underwent surgery for myomas (OR 1.34), in patients with comorbidities (OR 1.47) and those who underwent laparoscopic surgery (OR 1.92). The laparoscopic procedures doubled risk of operative complications compared with abdominal hysterectomy (6.1% vs. 3.6%).

The eVALuate[22] study consisted of two parallel randomized controlled trials: one comparing laparoscopic with abdominal hysterectomy and the other comparing laparoscopic with vaginal hysterectomy. Laparoscopic hysterectomy was associated with a higher rate of major complications that those performed via laparotomy (11.1% vs. 6.2%; $p = 0.02$). Conversion to laparotomy was included as a major complication; when conversions were excluded, there was no statistically significant difference between the two access routes. When vaginal access and laparoscopic access were compared, there was no difference in terms of complications. The study confirmed some advantages of laparoscopy such as less pain, shorter

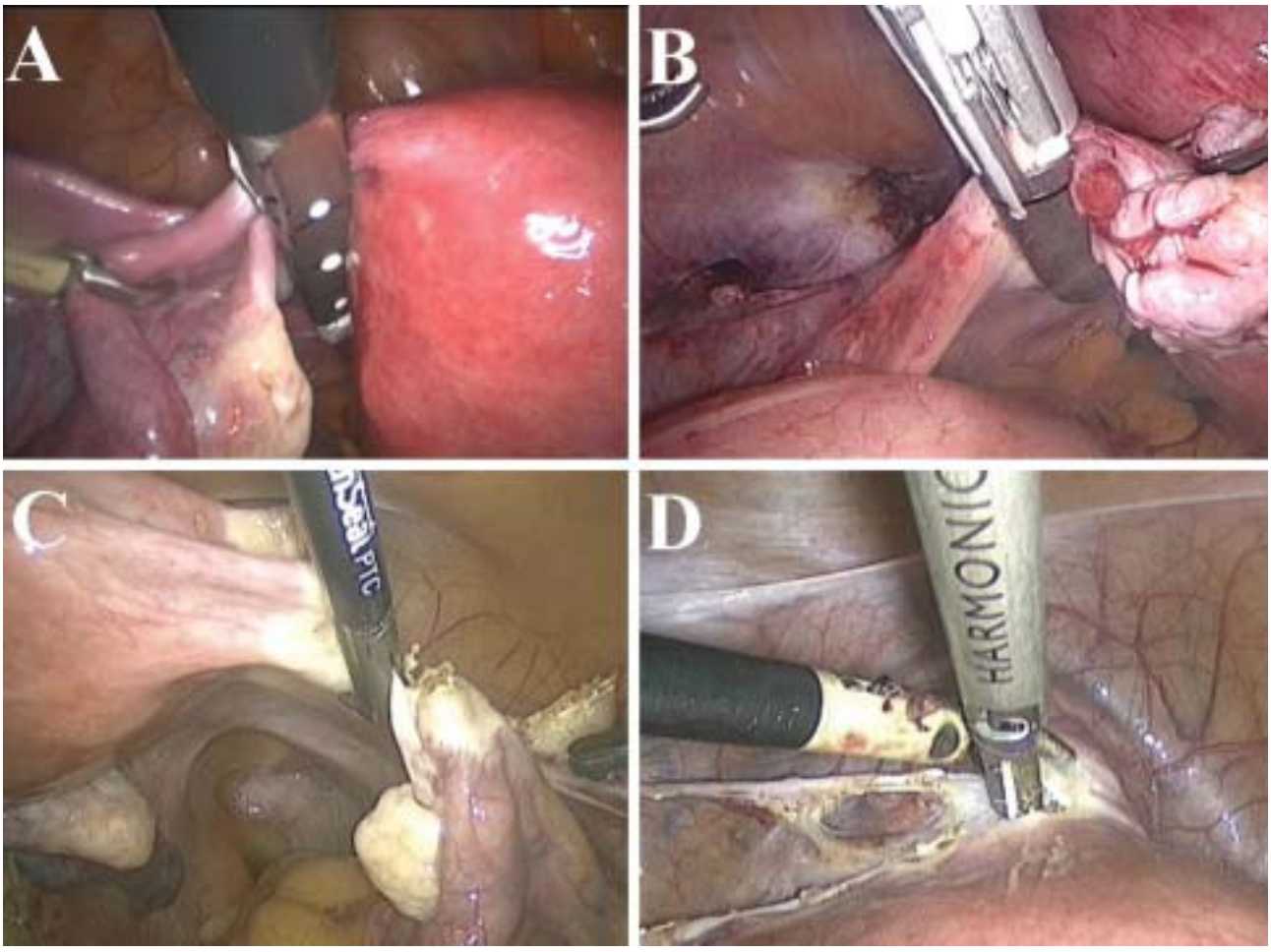

Figure 8 *- (A) Utilization of linear cutting endostaplers in a total laparoscopic hysterectomy. (B) Utilization of Ligasure® for the control of the infundibulo-pelvis a total laparoscopic hysterectomy. (C) Utilization of EnSeal® during the total laparoscopic hysterectomy. (D) Utilization of the Ultracision® harmonic scalpel in a total laparoscopic hysterectomy.*

hospitalization, a faster post-operative recuperation, and a better short-term quality of life when compared with laparotomy. Downsides included longer surgical time and a higher rate of urinary tract lesions.

In a meta-analysis, laparoscopy was associated with an increased risk of urinary tract lesions compared with abdominal hysterectomy (OR 2.61).[23] When ureteral and bladder lesion was separated, there were no increase risk of ureteral lesion with laparoscopy. Laparoscopy was associated with fewer infections (OR 0.32), fewer episodes of fever (OR 0.65), less blood loss (mean difference of 45.3ml) and a smaller drop hemoglobin values (0.55g/L) when compared with abdominal hysterectomy.

Similar findings were noted when comparing a vaginal and abdominal hysterectomy. There were no differences in the frequency of fistula formation, urinary dysfunction, sexual dysfunction or satisfaction of the patient when comparing the paths of access for the hysterectomy. No difference was observed in the need for blood transfusion, the occurrence of pelvic hematoma, vaginal vault infection, urinary tract infection, or thromboembolic events.

A recent series by Donnez et al[12] including 3190 laparoscopic hysterectomy showed that there is no increase in the rate of major complications when a laparoscopic hysterectomy is performed by experienced surgeons. No difference was found in the rate of ureteral lesions after vaginal hysterectomy (0.33%) and laparoscopic hysterectomy (0.25%). Bladder lesions occur in 0.44% of women who underwent a vaginal hysterectomy and in 0.31% of those who underwent a laparoscopic hysterectomy.

Several studies have observed that the incidence of the dehiscence of the vaginal vault after a laparoscopic hysterectomy is greater than after an

abdominal hysterectomy.[24] In the case of a laparoscopic total hysterectomy, the vagina is sutured using absorbable suture. One study that reviewed 7286 hysterectomies found an incidence of dehiscence of the vaginal wall of 4.93% after laparoscopic total hysterectomy, 0.29% after vaginal hysterectomy, and 0.12% after abdominal hysterectomy. The relative risk of vaginal vault dehiscence in laparoscopic total hysterectomy as compared with vaginal and abdominal hysterectomy was 21 and 53.2, respectively, and both were statistically significant.[25] There are no prospective studies comparing the methods of closure of the vaginal wall and in the risk of subsequent dehiscence, in part due to the infrequent occurrence of this complication. In the absence of data that might elucidate these findings, the recommendations for colpotomy and for the closure of the vaginal vault include: minimize the utilization of thermal energy in the vaginal vault, ensure adequate depth at the time of vaginal suturing, and be attentive to meticulous surgical technique, including hemostasis.

Another complication reported after laparoscopic hysterectomy is adnexal torsion. The prevalence of this complication is 7.91 per 1000 and occurs about 2.64 years after the laparoscopic hysterectomy in the study of Mashiach *et al.*[20] To prevent this competition, we routinely performed an adnexopexy at the time of the laparoscopic hysterectomy.

FINAL CONSIDERATIONS

The benefits of minimally invasive hysterectomy (laparoscopic or vaginal) are unquestionable when compared with open surgery. The possibility of exploring the abdominal pelvic cavity and of performing a safe oophorectomy, represent some of the advantages of laparoscopy in relation to the vaginal approach. The specific indications for each surgical technique remain uncertain. Nevertheless, the idea of laparoscopic hysterectomy is not to substitute a vaginal hysterectomy, but to increase the therapeutic arsenal of the gynecologic surgeon to carry out minimally invasive surgeries for a broad range of indications, avoiding the need for an abdominal hysterectomy in the setting of adnexal tumors, tubo-ovarian adhesions, endometriosis, previous pelvic surgeries, voluminous uteri, and obese patients.

RESUMO

A histerectomia é o procedimento cirúrgico ginecológico de grande porte mais comumente realizado em todo o mundo. As doenças benignas (ditúrbios menstruais, miomas, dor pélvica e prolapso uterino) são responsáveis por mais de 70% das indicações de histerectomia. Tradicionalmente, a histerectomia é realizada por laparotomia ou por via vaginal, mas recentemente a laparoscopia tem se tornado uma via de acesso alternativa com bons resultados. As vantagens da abordagem laparoscópica comparadas à cirurgia aberta incluem menor sangramento intra-operatório, menor tempo de permanência hospitalar, recuperação mais rápida e menor taxa de infecções de ferida e de parede abdominal, às custas de um tempo cirúrgico mais prolongado. Neste artigo abordaremos os detalhes técnicos da histerectomia total laparoscópica.

Palavras chave: Histerectomia Total. Laparoscopia. Técnica.

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Correspondence Address:
WILLIAM KONDO
Avenida Getulio Vargas 3163 Apt. 21
Curitiba, PR, Brazil 80240-041
Telefone: (41) 9222-1065
E-mail: williamkondo@yahoo.com
Site: drwilliamkondo.site.med.br

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Original Article

Laparoscopic Incisional Hernioplasty

Hernioplastia Incisional por Videolaparoscopia

MIGUEL PRESTES NÁCUL,[1] LAURA MOSCHETTI,[2] GUILHERME BEHREND SILVA RIBEIRO,[2] JOSÉ GUSTAVO OLIJNYK,[3] MAURO DE SOUZA SIEBERT JR.,[3] JAQUELINE BEHREND SILVA,[4] EDUARDO DIPP DE BARROS,[5] GUILHERME AREND PESCE[3]

Private Practice and Extension Course in Videolaparoscopic Surgery. Parque Belém Hospital, Porto Alegre, RS, Brazil.

[1] General and Trauma Surgeon. Full Member, SOBRACIL. Coordinator, Extension Course in Videolaparoscopic Surgery, Parque Belém Hospital; [2] General Surgery Resident, Hospital de Clínicas, Porto Alegre; [3] General and Trauma Surgeon. Instructor, Extension Course in Videolaparoscopic Surgery, Parque Belém Hospital; [4] Gynecologist. Full Member, SOBRACIL; Instructor, Extension Course in Videolaparoscopic Surgery, Parque Belém Hospital; [5] Gastrointestinal Surgeon. Full Member, SOBRACIL. Instructor, Extension Course in Videolaparoscopic Surgery, Parque Belém Hospital.

ABSTRACT

Objectives: the open repair of large size incisional hernias is associated with significant morbidity. The authors describe the surgical technique and present their experience with laparoscopic correction of medium and large size abdominal wall incisional hernias. **Patients and Methods**: patients accumulated over 13 years were analyzed retrospectively. 46 underwent laparoscopic incisional hernia repair with a follow-up of at least one year. **Results**: twenty patients were male and 26 female. The mean age was 48 years (27-78 years). Hernia size ranged from 5 to 25 cm in diameter. The mean surgical time was 105 minutes (30-240 min). There was one conversion to open repair, and one procedure was interrupted due to intraoperative suspicion of acute myocardial infarction. In 41 cases, we used polypropylene mesh and in three cases, coated mesh (one case Marlex PTFE - *Dual-Mesh Bard*® and in two cases, polypropylene mesh with silicone - *Microval*®). All mesh were placed intraperitoneally and fixed with transparietal propylene sutures tied at the anterior aponeurosis. Complementary fixation using titanium clips occurred in the majority of the cases. In two cases, fixation only involved helicoidal clips. No drains were utilized. All patients were discharged within 72 hours of surgery, except one that developed an enterocutaneous fistula. Major post operatory complications were identified in six cases, including one death because of intestinal perforation. There have been no recurrences to date. **Conclusion**: Laparoscopic incisional hernioplasty is an excellent option for incisional hernias treatment, with acceptable morbidity.

Key words: Laparoscopic Surgery; Incisional Hernia; Ventral Hernia.

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INTRODUCTION

Conceptually the incisional hernia (IH) consists of the rupture or loss of continuity of fascial closure, and can occur in any abdominal incision, but is most common in midline or para-midline incisions.[1] Advanced age, male gender, obesity, abdominal distention, pulmonary diseases, jaundice, anemia, malnutrition, operative wound infections, longitudinal incisions, closure techniques, and suture material are factors which influence the emergence of this disorder.[1,20] Beyond the aesthetic considerations, incisional hernias can cause a clinical presentation of acute abdomen due to entrapment and strangulation of the bowel loops, requiring emergency surgical treatment.[3]

IH continues to be one of the most common complications of abdominal surgical procedures, representing a significant source of morbidity and time lost from productive activity. The economic impact of this disorder is very significant.[1] The exact incidence of IH still has not been well defined, but there are reports in the literature that vary from 3% to 13%,[4,5] and up to 23% when associated with operative wound infections.[6]

The treatment of incisional hernias is complex, as it is complicated by high rates of recurrence and surgical infection. Recurrence rates after primary

incisional hernioplasty range from 25% to 63%[4,7,8,9,10] and are directly related to the size of the fascial defect. The relapse rate after open surgical correction of recurrent incisional hernias can exceed 50%,[11] and infection rates can reach 10%.[12]

Ideally, the technique of the repair should resolve the loss of abdominal wall substance and restore its dynamics. The use of prosthetic material generally fulfills these two imperatives,[13] resulting in a lower recurrence rate than with primary repair.[14] The relapse rates associated with the use of mesh were reported as being approximately 10%.[1]

The open repair of large IH is frequently associated with a painful postoperative recovery and a slow return to normal activities.[15] Recurrence after open repair is less if a mesh is used, but requires an extensive fascial dissection with the creation of flaps, increasing the rate of complications. The laparoscopic technique offers an alternative.[11]

The laparoscopic repair of IH began to be performed in the 1990s, always using a mesh in the intraperitoneal position and leaving the hernia sac *in situ*. The expectation was that the recurrence rate would remain similar to that of the open technique – up to 11% [11,17,18] – with a shortening of the postoperative recuperation and a decline in the rate of complications associated with large dissections,[16] and the potential benefit of decreased pain and a shorter hospitalization.[19]

The objective of this article is to report our experience with videolaparoscopic incisional hernioplasty during a period of 13 years, in the pursuit of better management of this disorder.

PATIENTS AND METHODS

All cases of laparoscopic incisional hernioplasty performed from 1996 to 2009 – both in the authors' private clinical practice as well as in the public healthcare system, the *Sistema Único de Saúde* (SUS), were reviewed.

The technique used consists of approaching the peritoneal cavity by an initial puncture under direct vision with a 10 mm trocar to establish the pneumoperitoneum. This puncture is located in the flank, contralateral to the area with previous surgery when the hernia is in the midline. Next, a 30° optic is introduced, the abdominal cavity is examined, two 5 mm trocar ports are positioned under laparoscopic vision, parallel to the primary port taking into account the position of adhesions normally encountered in these patients (Figure 1). Adhesiolysis is then performed to permit adequate assessment of the wall defect, which is the most delicate and time-consuming step of the procedure. It is important to stress that at this point electrosurgery should be used as little as possible and with the utmost maximum caution in order to avoid thermal lesions of the viscera.

Completing this phase of the surgery, the pneumoperitoneum is reduced, and one proceeds with measurement of the hernia defect and the preparation of the mesh (Figures 2 and 3). The mesh dimensions should be large enough to extend at least 3 cm in all directions for an adequate tissue-mesh interface. At this point, the locations for the introduction of the transparietal sutures that will be used to anchor the mesh are marked on the skin. Using 2-0 polypropylene (*Prolene*®), two to four cardinal sutures are tied in advance at the ends of mesh. The prosthesis is then introduced into the cavity. Through 2 mm incisions in the abdominal wall, a needle specially developed for this procedure is introduced into the cavity under direct vision to grab and exteriorize the threads anchored to the mesh (Figure 4). As needed, other sutures are then introduced through new orifices transfixing the mesh; they are again exteriorized, so that they are 3 to 6 cm apart and 1 cm from the edge of the mesh. All sutures are tied and buried subcutaneously. When available, titanium staples – preferably helical – are used between the transparietal sutures for the finishing of the edges of the reinforcement to prevent bowel loops or omentum from entering between the wall and the mesh (Figures 5 and 6). These smaller incisions are closed with *Micropore* ® tape. The closure of the 10 mm port is carried out in planes; the other 5 mm ports are closed exclusively at the skin level.

The patients are followed for at least one year after the surgical procedure.

RESULTS

Forty-six (46) patients were operated over a period of 13 years. There were twenty men and 24 women. The mean age of the patients was 48 years (27 to 78 years). The hernias ranged from five to 25 cm in diameter. The average surgical time was 105 minutes (30 to 240 minutes). There was a surgical conversion due to the consideration that the defect was less than 2 mm in diameter, opting for an

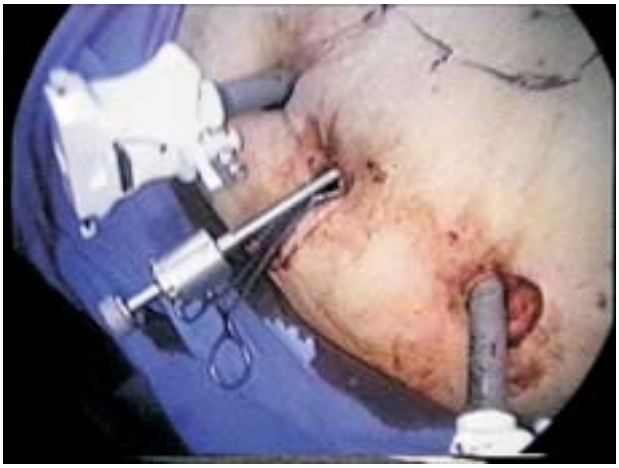

Figure 1 – *Placement of the ports.*

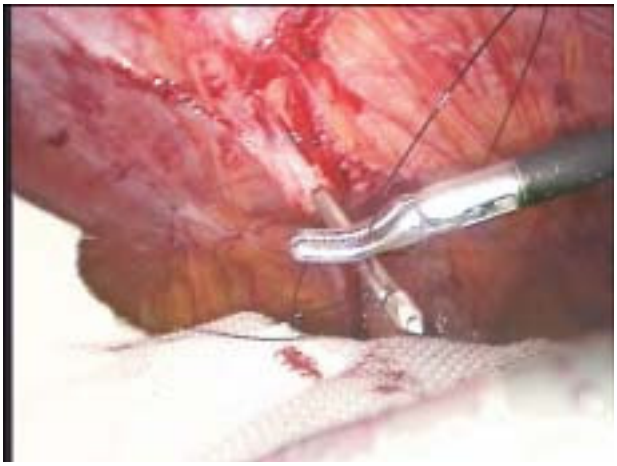

Figure 4 – *Transparietal sutures being tied.*

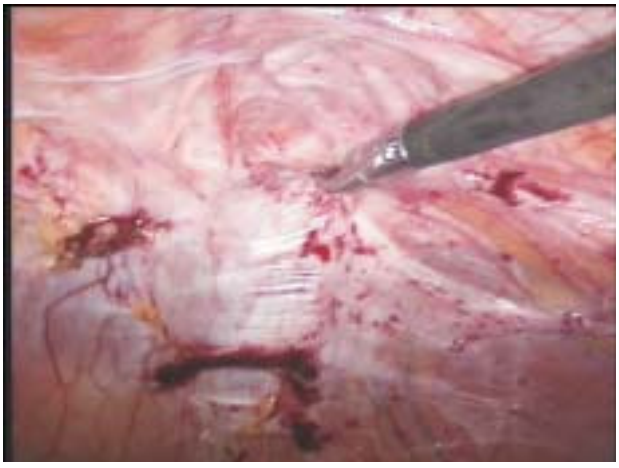

Figure 2 – *Hernia defect.*

Figure 5 – *Fixation of the mesh with helical staples.*

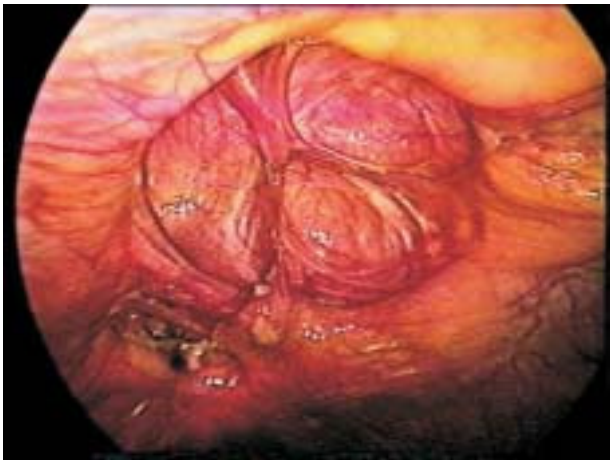

Figure 3 – *Hernia defect.*

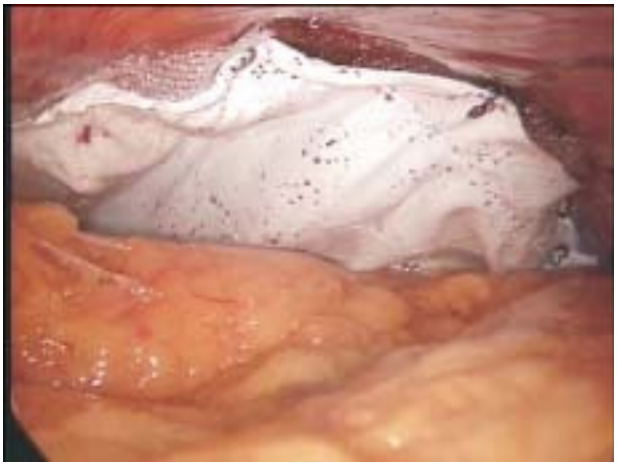

Figure 6 – *Final result: post-fixation of mesh with helical staples.*

open correction instead of an interior approach. Another patient, right at beginning of surgery, was suspected of having an intraoperative acute myocardial infarction. The surgeon opted to simply suspend the surgery; the diagnosis was subsequently "ruled out".

In 41 cases, a polypropylene mesh was used. In three cases coated meshes were used: in one case,

polypropylene and PTFE (*Bard Composix®)*) and in two cases, polypropylene mesh with silicone (*Microval®*). In all cases the mesh was positioned intraperitoneally and fixed with transparietal sutures tied in the anterior aponeurosis. Titanium staples complemented the fixation in most cases. In two cases, the fixation was performed with just helical staples. Drains were not used. All patients were discharged within 72 hours of the procedure, except one patient who developed an enterocutaneous fistula.

Major peri-operative complications were reported in six patients. There were two cases of operative wound infection, evolving with an abscess in the abdominal wall between the mesh and the skin. There was complete resolution after surgical drainage in one case, and in the other case partial removal of the mesh became necessary. There was one case of a lesion in the small intestine that went unperceived during the lysis of multiple adhesions that was complicated by an enterocutaneous fistula, partial infection of the mesh, and partial extrusion of the mesh. Another lesion of the small intestine occurred during the access to the peritoneal cavity under direct vision in the right flank of the abdomen. Once the lesion was perceived, it was sutured in two planes with absorbable surgical thread (3-0 Polyglactin) and the surgery proceeded with the execution of the planned procedure. There was one case of an incisional hernia in the site of the trocar. One patient with a large hernia in the midline corrected with a mesh that practically spanned the entire abdominal cavity returned five days after the surgery with a presentation of "acute abdomen". The patient was found to have diffuse peritonitis attributed to late perforation of the small intestine. The patient developed sepsis, was re-operated several times, but died on the twenty-fifth postoperative day. One patient who had undergone correction of a large midline incisional hernia that had recurred multiple times presented with a clinical picture compatible with an obstructive acute abdomen about three months after surgery and died before any new surgery, without having been evaluated by our service. All of the other cases were followed for at least one year, without any report of recurrence.

DISCUSSION

Hernioplasty of large incisional hernias is considered an advanced videolaparoscopic procedure that requires special equipment and instruments, and should be performed by surgeons trained and experienced in the technique. Access to the abdominal cavity should be done under direct vision, due to the risk of the visceral lesions, especially intestinal loops from the presence of peritoneal adhesions. Lesion of intestinal loops is a known complication of incisional hernioplasty with an incidence of 5% in open technique corrections and an incidence of 1% to 9.3% when the approach is laparoscopic. Patients with recurrent hernias, especially those that have previously used a mesh, should be approached with caution. If an enterotomy occurs during adhesiolysis, laparoscopic repair of the lesion is possible depending on the nature and severity of the lesion. In the presence of an enterotomy, options for the treatment of the hernia include a repair only with primary suture or, if this is not possible technically, the use of a mesh with absorbable material (*Vicryl Ethicon®*), followed by repair of the hernia months later. The use of conventional prostheses when faced with an enterotomy should, in general, be avoided due to the potential for infection. Alternately, some groups have used a mesh made of biomaterial in an attempt to achieve a lasting repair without running the risk of infection. In any case, any patient that presents complaints of abdominal pain, distension, or fever after a videolaparoscopic incisional hernioplasty should be evaluated for a possible intestinal lesion, especially if extensive adhesiolysis has been performed.[20]

One important aspect of the technique is that positioning of the mesh should be completely intraperitoneal. No sufficiently long follow-up of these patients exists that proves the long term safety of this technique, principally when using non-coated polypropylene mesh. The development of coated mesh in the late 1990s led to the intraperitoneal positioning of the mesh becoming more common. This technique permits a greater apposition of the mesh over the defect in the abdominal wall, which can reduce the chance of recurrence. Furthermore, the increase in intra-abdominal pressure keeps it in position, pressing it against abdominal wall, reducing possible separation of the mesh from the abdominal wall in the immediate post-operative period, facilitating its incorporation into surrounding tissues. The requirement that the mesh be placed intraperitoneally, directly adjacent to the intestine

can generate complications. Various experimental and clinical studies have shown that polypropylene and polyester mesh can cause severe intestinal adhesions, with devastating intestinal complications such as erosion and fistulas.[19] Polypropylene incorporates into the abdominal wall most efficiently, offering more resistance to traction. The disadvantage of this material has been the formation of dense adhesions between the mesh and the intra-abdominal content generating an abdomen potentially hostile to a new surgical approach, as well as the occasional enterocutaneous fistula.[21] Complications of subsequent surgical interventions after previous corrections of a ventral incisional hernia with polypropylene mesh positioned intraperitoneally were the focus of one study.[22] Repeat laparotomies after incisional hernioplasty with a polypropylene mesh – when the mesh is placed intraperitoneally – are associated with more intraoperative and postoperative complications. Therefore, intraperitoneal placement of polypropylene mesh in the repair of incisional hernias should be avoided, if possible.[22] Nevertheless, VRIJLAND and cols.[23] carried out a retrospective study of 136 patients with correction of incisional hernia using polypropylene mesh over a period of 16 years. The average follow-up was 34 months. No entero-cutaneous fistula developed. Operative wound infections occurred in 6% of the patients. Abdominal wall sinus occurred in two patients. There were no cases of persistent infection or cases where the mesh had to be removed due to infection. The authors concluded that the formation of entero-cutaneous fistula seems to be very rare after the correction of incisional hernias with polypropylene mesh, regardless of intraperitoneal placement, omental coverage, or closure of the peritoneum. BINGENER and cols.[24] sought to determine in incisional hernioplasty with the use of intraperitoneal polypropylene mesh if intestinal lesions and their complications can be impeded by the ultrasound guided interposition of omentum. Evaluating the results of 30 patients, the authors verified that 13 patients (43.4%) did not have a detectable ecographic signs of adhesions. Five patients demonstrated a piece between the match and the omentum. One patient developed adhesions between the left lobe of the liver and the mesh, and in only one case was adherence of the bowel to the edge of the mesh observed. The authors concluded that the laparoscopic repair of ventral incisional hernias with polypropylene mesh and interposition of omentum is not associated with visceral adhesions in the majority of patient. The polypropylene mesh can be used safely when omental coverage is available and sufficient. In a study reported by LEBER, polyester mesh has been associated with a greater risk of development of enterocutaneous fistula, infection, and recurrence of the hernia when compared with *Marlex®, Prolene®,* or *Gore-Tex®*.[25] In any case, it is recommended that mesh with these materials be separated, whenever possible, from the intestine. The majority of authors that describe a laparoscopic approach use compound mesh that provides a protective barrier to contact with intraperitoneal viscera. The *Gore-Tex Dual Mesh®* is composed of two layers of PTFE. One of the layers has 3 mm pores, which can be placed directly adjacent to the intestine. The other side has a microstructure that permits that the tissues develop adherence to the abdominal wall. There've been no reported cases of intestinal fistula secondary to intestinal erosion with this type of mesh. Other important property of the ePTFE is that it appears to be less easily infected then the other biomaterials. However, once an infection is established, this type of mesh should be removed. Another disadvantage of this type of mesh is its high cost, as well as the being relatively opaque, which generates technical difficulties during its placement.[19] Another type of mesh used is a compound of polypropylene on one side and ePTFE on the other (*Bard Composix®*). Ideally, this mesh combines the incorporation qualities of polypropylene with the greater resistance to adhesion is a property of ePTFE. Other compound mesh have been developed with these properties including *Composix Bilayer®* (polypropylene and ePTFE), *Proceed®* (low weight polypropylene and methylcellulose) and *Sepramesh®* (Sepra film and polypropylene). In our study, in all the cases in which polypropylene mesh was used, we sought to position the greater omentum between the intraperitoneal viscera and the mesh. Another option was to place methylcellulose (*Surgicel®*) on one of the sides of the polypropylene mesh, in order to try to diminish the incidence of adhesions.

One of the most critical aspects of laparoscopic technique which can affect the

recurrence rate is the method of fixation of the mesh. A variety of techniques are used to anchor the mesh to the abdominal wall. In the laparoscopic approach, the mesh is fixed using transparietal sutures and/or stapling. Staples are used in a uniform way, but the use of transparietal sutures varies from surgeon to surgeon, ranging from 26% to 97% of the cases. However, some authors have suggested importance of the fixation of anchoring transparietal sutures at intervals of 4 to 5 cm, circumferentially around the mesh to minimize the risk of migration.[20] The use of transparietal sutures is technically more complex, but reproduces an approach used in open surgery. The advantage of only stapling the mesh into position with various rows of staples is the ease of doing so, although some authors consider the depth of stapling to be insufficient. SOPER and cols.[21] in an experimental study demonstrated the quality of stapling in relation to transparietal suturing in terms of tensile strength, concluding that stapling was adequate for fixation of the mesh as long as they were helical staples. However, another experimental study in a swine model demonstrated that the tensile force of the transparietal fixation sutures is 2.5 times greater than that of the staples.[26] There are even clinical studies that report that the fixation of the mesh using just metal staples appears to be associated with an increase of recurrence.[16, 27]

In a randomized clinical trial BURGER and cols.[25] compared the rates of cumulative recurrence over 10 years in 181 patients that underwent hernioplasty without and with use of a mesh between 1992 and 1998. The recurrence rates were 63% and 32% respectively. Although there are no studies in the literature with a follow-up periods as long as this study, various other studies with two years or more of follow-up have shown recurrence rates of up to 11%[11,17,18] as well as a decrease in postoperative pain and shorter hospitalizations when the mesh was used for the repair of a hernia.[19] Another important aspect, that appears to be related with postoperative recurrence, is the positioning of the mesh in relation to the defect in the abdominal wall, suggesting that there should a mesh-tissue interface of at least 3 cm.[16] Laparoscopic techniques offer the additional advantage of identifying multiple defects that have not fully developed their hernia sacs and, therefore, still have not been identified on physical exam.

There are few articles in the literature comparing videolaparoscopic with open techniques in the treatment of IH, and most have low levels of evidence and low grades of recommendation. In their meta-analysis, CASSAR and MUNRO[15] found six articles comparing open incisional hernioplasty with laparoscopic hernioplasty which demonstrated a recurrence rate with laparoscopic surgery equal to or lower than open surgery. In five of the six articles a higher complication rate and a longer hospital length-of-stay in the group that underwent open surgery than in the group with mesh placement. The conclusion of the authors was that laparoscopic incisional hernioplasty is at least as effective and safe as the open surgery.

HENIFORD and cols.[27] published their nine year case series with 850 cases of videolaparoscopic incisional hernioplasty, with a complication rate of 13.2% and a recurrence rate of 4.7%, with the latter associated with large defects of the wall, obesity, previous repair, and perioperative complications. The average surgical time was 120 minutes and the mean hospitalization was 2.3 days. FRANKLIN in 2004, reported the findings of video-laparoscopic correction in 384 patients, after 11 years of experience, had a complication rate of 10.1%, and a recurrence rate of 2.9%, with a mean surgical time of 68 minutes and a hospital stay averaging 2.9 days.[28]

LOMATO and cols. compared the outcomes of 50 patients who underwent videolaparoscopic surgery with the outcomes of 50 patients who underwent the Rives-Stoppa open technique, with 20 months of follow-up.[29] The surgical time was similar for the two groups. The post-operative pain during the first 72 hours and the duration of the hospitalization were significantly shorter in the videolaparoscopic group. The complication rate (24%) and the recurrence rate (2%) of the videosurgery group was lower than that for open surgery (30% and 10%, respectively), with seroma the most frequent complication. In a cohort of 100 patients who underwent videolaparoscopic hernioplasty – of which 25 had a defect exceeding 15 cm – GIOVANNI and cols. found a complication rate of 23% and a recurrence rate of 3%, after 24 months of follow-up.[30] SOPER and cols. published their experience with 121 cases de videolaparoscopic incisional hernioplasty with a low conversion, short hospitalizations and acceptable complications and

recurrence rates.[20] The mean hospital stay of these patients was 1.7 days. The most common complication in the series was seroma, which occurred in 10.7% of the patients. Most of the seromas were described as small and self-limited, and were managed with observation, requiring aspiration in only six cases (5% of the repairs). In this series, 5% of the patients developed infections related to the hernia repair, including three cases in which the mesh needed to be removed. The patients that had their mesh removed ended up developing an incisional hernia again. Prolonged postoperative pain, greater than 6 to 12 weeks after the surgery, occurred in 3.3% of the patients. The principal location of the pain in these cases was close to the location of the trans-parietal sutures. Four enterotomies occurred, all in patients who had undergone repair of recurrent hernias, three of them already repaired with a mesh.

Videolaparoscopic surgery offers the benefit of avoiding large fascial dissections, thus diminishing dead space and avoiding the use of drains.[16] It also offers advantages in lower risk of surgical infection, less postoperative pain, and a shorter hospitalization.[29] And it allows a thorough inspection of the abdominal cavity and possible treatment of other diseases found. The laparoscopic approach seems to be effective in complex patients, such as the obese and in those in whom open repairs failed. Obese patients can especially benefit because of the small incisions, diminishing the complications of operative wounds.[20] Seromas are one of the most common consequences of videolaparoscopic incisional hernioplasty. This is due to the fact that the hernia sac is not dissected, leaving a chronic space where liquid can accumulate. Given the frequency with which this problem occurs, some authors have questioned its classification as a complication. The aspiration of the seroma should be reserved for those cases that persist or that are symptomatic or when there is diagnostic uncertainty. Steps to minimize the risk of infection should include the elimination of potential sources of infection before surgery, antibiotic prophylaxis, limiting the contact of the mesh with the skin, careful preparation of the skin, and general hygiene on the part of the patient.[20] The initial management of prolonged postoperative pain (more than 6 to 12 weeks after the operation) should be conservative with the administration of anti-inflammatory medications, applying ice to the affected area, and injection with local anesthetic or corticosteroids. Removal of the transparietal sutures can be necessary for persistent symptoms that don't respond to conservative treatment.[20]

CONCLUSION

Videolaparoscopic surgery offers obvious advantages demonstrated by different authors in their case series.[11,12,13,15,17,19,20,27,28,29,30] The technique produces a repair without tension, facilitates adhesiolysis by magnifying the image by using the videolaparoscope, and permits inspection of the entire abdominal cavity. It also eliminates the need for large fascial dissections and for drainage, diminishing the risk and the morbidity from a surgical infection. Thus, they tend to provide a faster postoperative recovery and a better aesthetic result.

Although our sample is relatively small, the findings corroborate the data found in the literature. The technique used in the same published by various authors with the placement of the mesh in an intraperitoneal position fixed by transparietal sutures attached to the aponeurosis and buried in the subcutaneous tissue and complemented with stapling preferably with helical staples. The results have been encouraging, as they associate the classic benefits of videolaparoscopic surgery to a low rate of recurrence and complications. Intestinal loop lesions are the greatest risk; the occurrence of such lesions is directly related to the number of intestinal adhesions secondary to previous surgery and the hernia defect itself.

The videolaparoscopic incisional hernioplasty seems to be a safe option for the treatment of incisional hernia, with recurrence rates similar to open surgery with lower morbidity. The principal limitations are the size of the hernia – which can hamper access by videolaparoscopy when very large – and the high cost of compound mesh. There is a dearth of randomized prospective studies with long term follow-up so that videolaparoscopic hernioplasty incisional can be recognized as the technique of choice in the treatment of this disease. Despite the technologic advances of videosurgery and prosthetic materials and the abilities of the surgeons, there still is not an ideal technique, free of recurrence and morbidity. Even with the growing number of publications addressing this subject, many of the fundamental questions continue without answers. Meanwhile, incisional hernias will continue to be a challenge for the general surgeon.

RESUMO

Objetivos: o reparo aberto de hérnias incisionais de grande porte está associado à significativa morbidade pós-operatória. The autores descrevem a técnica empregada e apresentam sua experiência com a correção de hérnias incisionais de médio e grande porte da parede abdominal por videolaparoscopia. **Pacientes e Métodos:** foram analisados retrospectivamente, ao longo de 13 anos, 46 pacientes submetidos à hernioplastia incisional videolaparoscópica, com seguimento pós-operatório mínimo de um ano. **Resultados:** vinte pacientes pertenciam ao sexo masculino e vinte e seis ao sexo feminino, com idade média de 48 anos (27-78 anos). The hérnias variaram de 5 a 25 cm de diâmetro. O tempo cirúrgico médio foi de 105 minutos (30-240 minutos). Houve uma conversão para cirurgia aberta e um procedimento foi interrompido por suspeita de infarto agudo do miocárdio trans-operatório. Em 41 casos foram utilizadas telas de polipropileno. Apenas em três pacientes, foram utilizadas telas revestidas (em um caso, polipropileno e PTFE - D*ual-Mesh Bard®* e em dois casos, telas de polipropileno e silicone - *Microval®*). The telas foram posicionadas intra-peritonealmente e fixadas por suturas de polipropileno passadas transparietais, atadas na aponeurose anterior, com fixação complementar de grampos de titânio. Em dois casos, fixou-se apenas com grampos helicoidais. Drenos não foram utilizados. Todos pacientes receberam alta em até 72 horas, exceto um que apresentou fístula enterocutânea. Complicações peri-operatórias maiores ocorreram em 6 pacientes, incluindo um óbito por perfuração intestinal. Não houve recidiva até o presente momento. **Conclusão**: a hernioplastia incisional por videolaparoscopia é uma boa opção para o tratamento das hérnias incisionais, com morbidade aceitável.

Palavras chave: Cirurgia Laparoscópica; Hérnia Incisional; Hérnia Ventral.

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Correspondence Address:
MIGUEL PRESTES NACUL
Rua dos Andradas 1781/404
Centro, Porto Alegre, RS
91410-001
Telefone/Fax: (51) 3227-3244
E-mail: miguelnacul@gmail.com

Brazilian Journal of Videoendoscopic Surgery

Original Article

Transumbilical Single-Port Laparoscopic Cholecystectomy

Colecistectomia Single-Port Laparoscópica

CAROLINA PAIVA REBOUÇAS DE ANDRADE, MD[1]; PRISCILA SARAIVA OLIVEIRA, MD[2]; RICARDO ZORRON, PROFESSOR OF SURGERY, MD, PHD[3]

Research performed at the Department of Surgery –Lourenço Jorge Municipal Hospital, Rio de Janeiro, Brazil. [1.] Surgeon, Department of Surgery. Lourenço Jorge Municipal Hospital, Rio de Janeiro, Brazil; [2.] Surgeon, Department of Surgery. Lourenço Jorge Municipal Hospital, Rio de Janeiro, Brazil; [3.] TCBC- Titular Colégio Brasileiro de Cirurgiões, Titular SOBRACIL, SAGES Member. Professor and Chairman, Department of Surgery. University Hospital Teresopolis HCTCO- FESO, Rio de Janeiro, Brazil. Department of Surgery. Lourenço Jorge Municipal Hospital, Rio de Janeiro, Brazil;

ABSTRACT

Objectives: The well-established advantages of the laparoscopic approach have enabled this procedure to gain rapid worldwide acceptance. With advances in the field of minimally invasive surgery, single-incision laparoscopic surgery (SILS) was developed with the aim of reducing the invasiveness of traditional laparoscopy. The authors propose a single-incision laparoscopic (SILS) cholecystectomy as a step toward less invasive surgical procedures. We report a series of transumbilical single-port cholecystectomies performed with only a single umbilical scar. **Methods:** Transumbilical single-port cholecystectomies performed with three 5mm to 10mm incisions through the umbilicus and the introduction of three standard laparoscopic trocars through this one incision. The operative technique, along with the results of the first 11 patients operated in this way is described. **Results:** Eleven women with a mean age of 47 underwent the technique. Mean operative time was 74 min. Few complications were recorded after 30 days. One patient developed a local umbilical granuloma. Analgesic use was limited to first 24 hours. Cosmetic result was satisfactory in all cases. **Conclusion:** Transumbilical endoscopic surgery is feasible, safe and effective; and constitutes another option for scarless abdominal surgery.

Key words: Single Port Surgery, Single Access Surgery, Laparoscopy, Natural orifice surgery; NOTES; Cholecystectomy, SILS, LESS, SPA.

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INTRODUCTION

Cholecystectomy, the procedure most frequently performed laparoscopically worldwide, has been recognized since 1992 as the gold standard procedure for gallbladder removal. The well-established advantages of the laparoscopic approach have enabled this procedure to gain rapid worldwide acceptance. These advantages include better cosmetic results, less postoperative pain, and shorter recovery time than with open cholecystectomy. Increasingly, as suggested by the growing number of case reports, patients are asking surgeons to be operated without external scars.

The introduction of natural orifice transluminal endoscopic surgery (NOTES) has enabled the treatment of digestive diseases such as acute appendicitis and gallstones, and even the creation of some kinds of fundoplication by means of a flexible scope (with multiple instruments) introduced through the stomach, rectum or vagina. This approach has opened a new surgical frontier in which the patient is operated on with less pain, less discomfort, and even without any scar.[1-8]

Single-access or single-port surgery holds the promise of advancing minimally invasive surgical techniques to the next frontier with the use of only a single laparoscopic incision or multiple incisions that are placed within a single site such as the umbilicus to eliminate any visible abdominal scars. For example, rather than performing a laparoscopic

cholecystectomy through the conventional four laparoscopic trocars, the procedure would be performed through a single port or single incision placed within the umbilicus which then will be used for extraction of the gallbladder. A potential disadvantage with the single incision technique is restriction in the degree of movement of laparoscopic instruments and camera. This study presents a preliminary clinical series of a novel technique for transumbilical cholecystectomy employing existing instruments.

METHODS

All the patients were informed about the intervention technique and provided written consent. Prospective data regarding demographic data, operative time and bleeding estimation, and postoperative course and complications were recorded.

SURGICAL TECHNIQUE

The patient was positioned in a prone position with reverse Trendelenburg angulation, and the patient's right side was also tilted up. Using an open Hasson technique, a 2.5 cm incision was made through the umbilicus with dissection down to the linea alba. A 1 cm incision was made in the fascia and the peritoneum opened under direct vision. After placement of 0 Vicryl fascial stay sutures, a 10-mm blunt trocar was introduced into the abdomen. Establishment of a pneumoperitoneum using carbon dioxide to an intraabdominal pressure of 12 mmHg was achieved. A 30º 10-mm laparoscope was inserted through the trocar and a full diagnostic laparoscopy performed. Two 5-mm trocars were then inserted through separate areas of fascia in the midline within the same umbilical skin incision under direct vision, in some cases we were able to use one or two 10mm trocars (Figure 1). The operator stood at the left side of the patient with the camera holder to the patient's right side. When necessary, a 3-0 Mononylon suture was tied to the infundibulum through a transparietal straight needle, which allowed for improved visualization of Calot's Triangle. The left 5mm trocar was initially used to allow gallbladder retraction using a grasper (Figure 2). Dissection of gallbladder structures was achieved in the standard fashion using a Maryland Grasper in the right hand to manipulate the gallbladder, and an alligator grasper in the left hand for retracting the gallblader fundus. Once the cystic artery and duct were exposed, they were clipped separately using a 10-mm clip and divided (Figure 3). In cases when only 5mm trocars are used, mostly ligature was performed by external tied knots of polypropilene 2.0. The gallbladder was then dissected

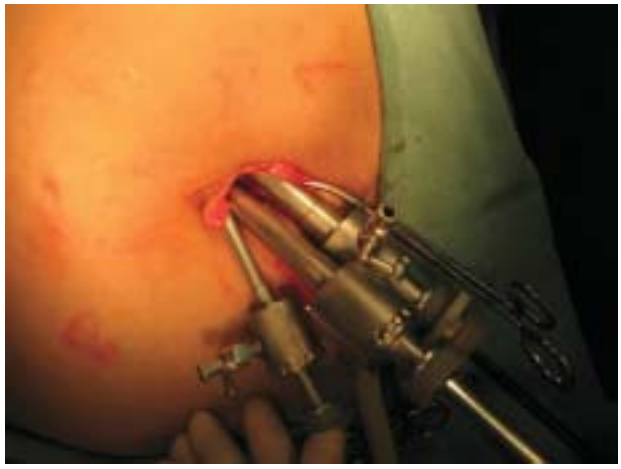

Figure 1 - *Introduction of 3 trocars inside the umbilical incision by 3 separate fascial wounds.*

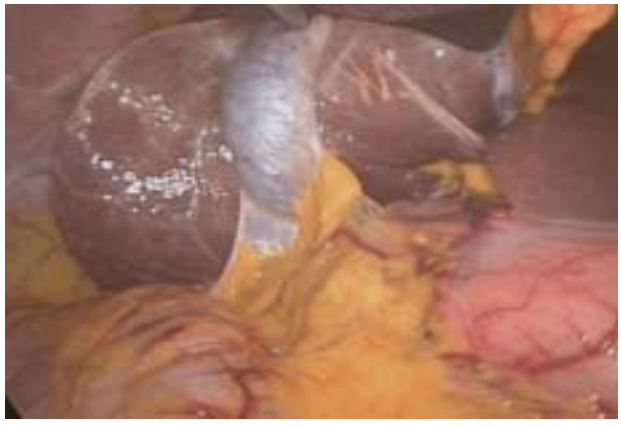

Figure 2 - *Retraction of the gallbladder fundus by the left 5mm trocar.*

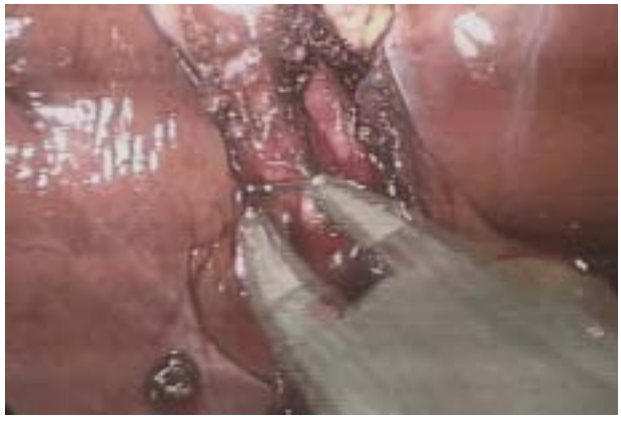

Figure 3 - *After dissection of the Calot's Triangle, 5mm clips are used to ligate the cystic duct and artery.*

free from the liver bed using diathermy and a combination of repositioning the traction grasper for better exposure. Prior to complete removal of the gallbladder from the liver bed, hemostasis was achieved. Following complete dissection of the gallbladder, it was removed through the umbilical incision without the use of a bag in all cases (Figure 4). To allow this, the two or three separate incisions in the umbilical fascia sometimes had to be combined into a single larger incision. Closure of the aponeurosis was achieved using running 0 vicryl sutures. Skin closure was performed using 4-0 Mononylon suture.

RESULTS

A total of 11 female patients ranging in age from 24 to 66 (mean of 47) underwent the technique; data was recorded prospectively. Mean operative time was 74 min. Operative bleeding was a mean of less than 50ml. One patient required the addition of one subcostal laparoscopic 5mm trocar due to poor exposure of cystic structures. Colangiography was necessary in one patient. Few complications were recorded after 30 days. One patient developed a local umbilical granuloma, and the Vicryl suture was removed after 60 days. Analgesics were used only in the first 24 hours.

Resumption of oral intake was initiated on the same operative day, all patients were discharged within 24 hours of surgery.

The cosmetic result was satisfactory in all patients. A previous umbilical piercing remained untouched in two patients (Figure 5).

DISCUSSION

During recent years, laparoscopic surgery has developed rapidly. With great technical progress, the visualization and handling of the instruments has improved enormously. For this reason many surgical diseases can be treated laparoscopically with the same standard of safety as conventional surgery. Applying laparoscopic techniques, operations are less traumatic; there is less postoperative bowel ileus, which in turn allows faster progression of postoperative feeding. The cosmetic results of laparoscopic procedures are much better than those of traditional operations. Postoperative pain is reduced, which results in faster mobilization and a lower number of immobilization-

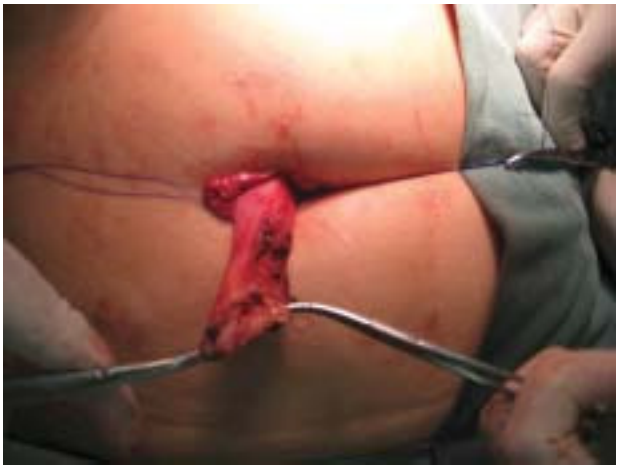

Figure 4 - *Umbilical extraction of the gallbladder.*

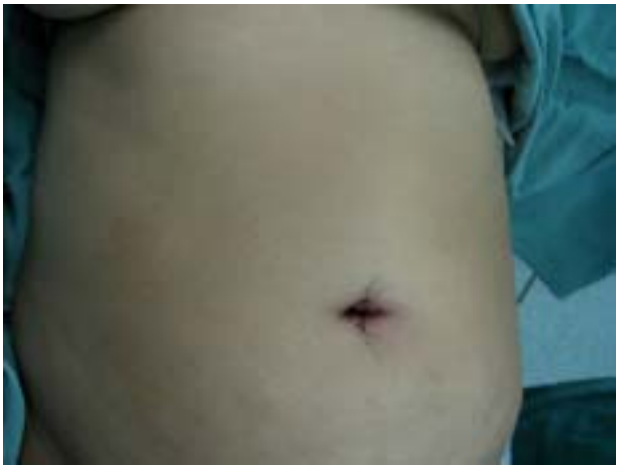

Figure 5 - *Cosmetic aspect after single access umbilical cholecystectomy.*

associated complications, such as venous thrombosis and pulmonary embolism.[9-10]

Furthermore, with laparoscopic procedures there is less pneumonia, less use of analgesics, and shorter hospital stays. In summary, the primary benefits for the patient include a faster recovery and better cosmetic result. Laparoscopic surgery not only benefits from technical improvements; since successfully applying the laparoscopic technique to cholecystectomy, many surgeons have attempted to reduce the number and size of ports used in laparoscopic cholecystectomy with the aim of reducing pain, disfigurement, and disability.[11,12]

These efforts resulted in the development of natural orifice transluminal endoscopic surgery (NOTES), introduced in 2004, and more recent invention of singleport access laparoscopy (SPA).[13] After pioneering work published by Zorron et al in

2007 using the transvaginal approach to cholecystectomy,[3] other groups followed and performed the transvaginal technique combined with laparoscopic assistance.[4-8] The natural orifice transluminal endoscopic surgery (NOTES) approach, aims to avoid transabdominal incisions completely[14,15] by avoiding external incisions using a natural orifice, such as the mouth, anus, or vagina, followed by making an internal incision to insert the laparoscopic instruments. Therefore, a viscerotomy is performed. Although NOTES may be technically feasible, its use is limited by difficulty in access, lack of appropriate instruments, and concern over breaking the sterility barrier.

Transumbilical single-port surgery or single incision laparoscopic surgery (SILS) may be an alternative to NOTES, offering the potential of a technically easier operation, avoiding possible complications and obtaining the same abdominal cosmetic result. However, single access surgery may not reproduce all the advantages expected for natural orifice surgery, as the umbilicus is a natural scar, not an orifice, and the surgical wound produces somatic pain rather than visceral pain. Regarding this evolving concept, potential advantages in NOTES regarding avoidance of incision-related complications and somatic pain are absent in SILS.

Single Access Surgery has already been implemented clinically and is a rapidly evolving field,[16,17] whereas NOTES has major barriers that limit its clinical application, such as spillage of gastric, urinary, or colonic contents within the abdomen, potential complications of leakage from a gastrotomy or colotomy, the difficult task of a viscerotomy closure, and difficulty maintaining spatial orientation.[15,18] Moreover, NOTES requires special instruments, while SPA can be performed with standard laparoscopic instruments. Also, it is always possible to convert a single-port surgery to a multi-port conventional laparoscopic procedure as necessary, such that surgical safety and outcomes remain uncompromised in single port surgery.

Single-access laparoscopic surgery was reported in the literature more than a decade ago for cholecystectomy,[19,20] but it did not gain widespread use because of some technical barriers. Recently, a transumbilical laparoscopic cholecystectomy scarless technique with a 1-mm specially designed wire was developed,[21] and represented an advancement for a virtually scarless surgery. However, it is hazardous to dissect Calot's triangle with one hand. Other groups reported variations of traditional laparoscopic cholecystectomy, such as needlescopic laparoscopy (minilaparoscopy) and using fewer trocars motivated by reducing surgical invasiveness.[22-32]

This study approached the "single-port" concept, consisting in a single-incision with multiple trocars, involving placing multiple, commercially available, standard laparoscopic ports through a single periumbilical incision. Choosing ports that have a lower external or internal profile allows for a wider range of instrument motion and the best combination of ports depends on the procedure being performed, but it typically includes three or four ports, each 10 to 5-mm or smaller. Transumbilical endoscopic surgery using normal laparoscopic trocars inserted intra-umbilically is feasible, safe and effective; and constitutes another option for abdominal surgery avoiding visible scars.

Objetivos: As vantagens bem estabelecidas da abordagem laparoscópica permitiram que está técnica tivesse aceitação rápida no mundo inteiro. Com os avanços no campo da cirurgia minimamente invasiva, a cirurgia laparoscópica por incisão única (SIL) foi desenvolvida com o objetivo de reduzir a invasão da laparoscopia tradicional. Os autores propõem uma colecistectomia laparoscópica por incisão única (SIL) como um passo em direção a procedimentos cirúrgicos menos invasivos. Nós relatamos uma série de colecistectomias por porta única transumbilical.

RESUMO

Objetivos: As vantagens bem estabelecidas da abordagem laparoscópica permitiram que está técnica tivesse aceitação rápida no mundo inteiro. Com os avanços no campo da cirurgia minimamente invasiva, a cirurgia laparoscópica por incisão única (SIL) foi desenvolvida com o objetivo de reduzir a invasão da laparoscopia tradicional. Os autores propõem uma colecistectomia laparoscópica por incisão única (SIL) como um passo em direção a procedimentos cirúrgicos menos invasivos. Nós relatamos uma série de colecistectomias por porta única transumbilical. Métodos: Foram realizadas 11 colecistectomias por porta única transumbilical. Foram realizadas três incisões de 5 a 10 milímetros através do umbigo, com a introdução de três trocartes laparoscópicos tradicionais através desta incisão única. Resultados: Onze mulheres com idade média de 47 anos foram submetidas à esta técnica. O tempo operatório médio foi de 74 min.

Poucas complicações foram registradas após 30 dias. Uma paciente desenvolveu um granuloma umbilical. O uso de analgésico limitou-se às primeira 24 horas. O resultado estético foi satisfatório em todos os casos. Conclusão: cirurgia endoscópica transumbilical é viável, segura e eficaz, e constitui outra opção para a cirurgia abdominal praticamente sem cicatriz.

Palavras chave: cirurgia por incisão única, laparoscopia,NOTES; colecistectomia; SILS; LESS.

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Correspondence Address:
RICARDO ZORRON
Department of Surgery
Universuty Hospital Teresopolis HCTCO-FESO
E-mail: rzorron@terra.com.br

INFORMATION FOR AUTHORS

1. Objectives

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- Case Report(or Clinical Meeting): with critical analysis and discussion;
- Clinical Observation: should have critical analysis and discussion;
- Epidemiologic Statistics: with critical analysis and discussion;
- Description and Evaluation: of methods or procedures, with revision, critical analysis and discussion;
- Opinion and Analysis: of philosophical, ethical and social aspects regarding the area of study;
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- Manuscripts should be typed double-spaced with up to 25 lines per page.
- Pages should be numbered consecutively (numbers should be in the upper or lower right corner). The first page should be the Title Page.
- Each section should start on a new page.
- Manuscripts should be printed on one side of a 216x279mm or A4(212x297mm) white sulphite paper with margins of 25mm.
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- Abstract/Key words;
- Text pages and Acknowledgments;
- References;
- Tables (one in each page, separately);
- Illustrations;
- Legends;
- Abbreviations.

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All manuscripts will be subject to a process of anonymous editorial review, therefore the name and address of authors should only be in the Title Page with identification as it is not going to be sent to the reviewers. The authors should verify if there is any identification on the text to avoid identification.

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The abstract is mandatory. It should be up to 250 words. Every abstract should be written in an informative style. Depending on the abstract it should contain the following headings:

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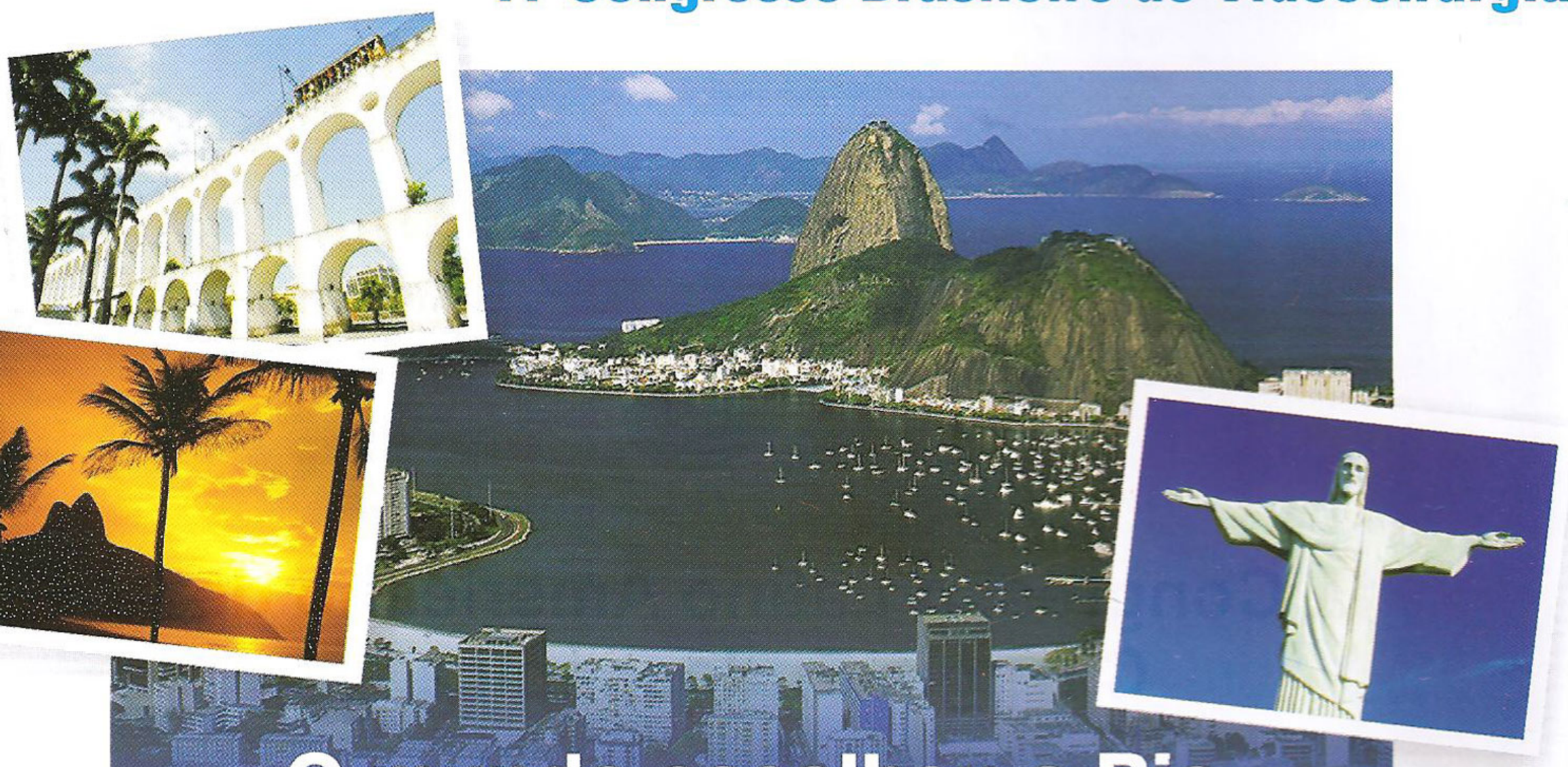

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