COMPARATIVE STUDY OF PRESSURE PROFILE TEST VERSUS PALMER'S TEST IN PREDICTING CORRECT INTRA-PERITONEAL PLACEMENT OF VERESS NEEDLE PRIOR TO INSUFFLATION DURING LAPAROSCOPIC SURGERIES

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Abstract

Background: Laparoscopy is an important and common method of accessing the peritoneal cavity to perform many types of gynaecologic surgery. Clearly safety of entry is of the utmost importance and despite debate regarding the preferred method of achieving peritoneal access; there is no single technique with demonstrated superiority.

Methods: All consecutive patients who had a legitimate indication and declared fit to undergo a laparoscopic operation in the Department of Obstetrics and Gynaecology, K D Medical College, Hospital & Research Center; Mathura (UP) underwent a prospective observational study. There were no exclusion criteria.

Results- In normal weight category sensitivity, specificity, PPV, NPV, were 0.99, 1, 1 and 0.75 respectively. In overweight category sensitivity and PPV were 1, and 0.97 respectively. In obese category sensitivity, PPV, were 1 and 1 respectively

Conclusion: So we can see that pressure profile test shows higher sensitivity and PPV across all grades of surgeons as well as higher specificity and NPV.

Keywords: Sensitivity, specificity, overweight.

Introduction

Laparoscopic surgical advances have accelerated remarkably over the past decades. What was initially a way for diagnostic purpose and minor procedures like tubal sterilisation has evolved into a more coordinated system for major surgical procedures.

Operative laparoscopy plays a major role in the management of benign and malignant gynaecological conditions and has several advantages over conventional laparotomy.

To minimise entry related complications, several techniques and technologies have been introduced during the last 50 years. These include the 'classic' or closed entry technique, the open (Hasson) entry, the direct trocar entry, shielded trocar, optical Veress and optical trocars.¹

Closed entry technique using the Veress needle to create pneumoperitoneum is used by 90% of gynaecologists in majority of centres and remains the most common method taught to gynaecological trainees. By contrast, general surgeons favour the open technique described by Hasson in 1971 citing lower rates of viscus injury and failed insufflations^{2,3}

Creation of a pneumoperitoneum is the most critical step of a laparoscopic procedure. There is still no consensus regarding the best method of gaining access to the peritoneal cavity for creating pneumoperitoneum.⁴

The Veress needle puncture is the most commonly applied technique.⁵ In a study with 1, 55,987 laparoscopic procedures there was an 81% rate of Veress needle usage.⁶

Although transfundal, tranforneal, suprapubic and Palmer's point insufflation routes have been described,⁷ 98% of gynaecologists still utilise either a sub- or intra-umbilical insertion on the basis that this site represents the thinnest portion of the anterior abdominal wall.

After insertion and during insufflations, however, the exact position of the tip of the Veress needle is not always known. Errors in puncturing and insufflations are frequent and may cause severe iatrogenic injuries.⁸

Although the overwhelming majority of reported laparoscopic complications result from improper Veress needle placement, the safety tests commonly used to determine correct placement subjective and not always reliable.

The commonly performed tests to determine correct Veress needle placement are:

1. The double click test.
2. The aspiration test (Palmer's test).
3. The saline solution hanging drop test.
4. The 'hiss' test.
5. The syringe test.
6. Serial intra-abdominal gas pressure measurement test (Pressure profile test)

Whereas all these tests may offer surgeons some sense of security and comfort, they are not foolproof because misplacement of the Veress needle continues to occur.^{9,10}

However, in low risk patients, no single method has been shown to be superior to others in avoiding entry related Veress needle injuries during closed laparoscopy.

Previous reports describe methods to increase the likelihood of correct Veress needle placement during the initial stages of laparoscopic entry though there are few data that assess the reliability of these indicators.^{11,12}

The tests performed to check whether the Veress needle is correctly positioned lack objective criteria of validation.

A prospective study reported that most of these tests provided very little information in Veress needle placement during closed laparoscopy.

In fact, it was established that the initial pressure is the only valuable parameter reflecting correct needle placement.

A recent retrospective study have concluded that initial intra-peritoneal pressure of 10 mmHg or below indicates the correct placement of the Veress needle, regardless of woman's BMI, parity or age.¹³

Keeping in mind the ever increasing popularity and advantages of laparoscopic techniques in the management of gynaecological ailments and the versatility of laparoscopy which ranges from simple diagnostic procedures to the extensive ones and also the future prospects,

We have conducted a prospective observational study to:

- a) Compare the values of Palmer's test and pressure profile test in predicting correct placement of Veress needle.
- b) Assess the related factors that may influence the sensitivity and specificity of these tests.

Materials and Methods

1. STUDY AREA:

Department of Obstetrics and Gynaecology, K D Medical College, Hospital & Research Center, Mathura (UP)

2. STUDY POPULATION:

Consecutive patients undergoing elective laparoscopic surgery in Department of Obstetrics and Gynaecology, K D Medical College, Hospital & Research Center, Mathura (UP).

3. STUDY PERIOD:

June 2019 to December 2019

4. SAMPLE SIZE:

The sample size was 150.

5. SAMPLE DESIGN:

All consecutive patients who had a legitimate indication and declared fit to undergo a laparoscopic operation in the Department of Obstetrics and Gynaecology, K D Medical College, Hospital & Research Center, Mathura (UP) underwent a prospective observational study. There were no exclusion criteria.

6. STUDY DESIGN:

Prospective observational study.

7. PARAMETERS STUDIED:

- (a) Sensitivity, Specificity, Negative and Positive predictive values of Palmer's test and pressure profile tests.
- (b) BMI
- (c) Previous abdominal surgery
- (d) Seniority of surgeon.
- (e) Site of entry of Veress needle chosen by surgeon.
- (f) Indication of laparoscopy
- (g) Results of tests done.
- (h) Complications.

8. STUDY TOOLS:

- a. BHTs of patients.
- b. Relevant history of patients.
- c. Patient related factors for BMI.
- d. Laparoscopic OT set up and instruments including Veress needle.

9. STUDY TECHNIQUE:

This study was done after getting approval from the concerned authorities and was performed in the Department of Obstetrics and Gynaecology, K D Medical College, Hospital & Research Center, Mathura (UP). Total 150 consecutive patients undergoing elective laparoscopic surgery were recruited in this study without any exclusion criteria from June 2019 to Dec 19. Required information such as age previous abdominal surgery, indication of laparoscopy, BMI of patients, site of entry of Veress needle, complications were collected. Preoperative preparation of patients included a residue free diet. Majority of the cases were done under general anaesthesia with tracheal intubation and mechanical ventilation and placed in the lithotomy position. While undergoing laparoscopic surgery, just prior to insufflation

two safety tests were performed to assess correct intra-peritoneal placement of Veress needle namely Palmer's test and pressure profile test.

PALMER'S TEST:

A resistance free, disposable syringe filled with 5 ml normal saline was attached to the Veress needle with the flow tap open. Syringe was aspirated to ensure no blood or faecal material was present and 5 ml of sterile normal saline was injected which should flow with minimal resistance. Syringe was then re-aspirated to ensure that the fluid was not trapped in a loculated area bound by adhesions or within extra-peritoneal cavity.

For our study test was documented positive when there was no immediate aspirate or resistance on injecting normal saline and no fluid was obtained on re-aspiration.

PRESSURE PROFILE TEST:

The gas tubing was primed with CO₂ before connecting to Veress needle to purge all the air from the line, and the flow rate was set at 1 litre/minute. The first five pressures registered by the gas insufflator were recorded at five seconds interval. According to previous studies pressures less than 10 mmHg indicated most likely correct intra-peritoneal placement.^[1]

10. PLAN FOR ANALYSIS OF DATA:

Collected data on different variables were analysed with appropriate tests using statistical software SPSS version 17.

Sensitivity, specificity, positive predictive and negative predictive values were calculated.

Results

Table 1: Division of patients according to age

AGE GROUP (IN YEARS)	NUMBER(n =150)
Less than 20	11(7.33%)
21-40	99(66%)
41-60	40 (26.67%)

As evident from the table most of the patients (66%) belonged to reproductive age group.

Table 2: Division of patients according to bmi

BMI	NUMBER OF PATIENTS (n=150)
Less than 18.5	11 (7.33%)
18.5-24.9	74 (49.33%)
25-29.9	35 (23.34%)
More than 30	30 (20%)

Patients were categorized as per WHO classification of BMI.

As the table shows about half of the cases i.e.74 (49.33%) falls into the category of normal weight with BMI range 18.5 to 24.9. Only 11 (7.33%) cases were in underweight category whose BMI was below 18.5.

35(23.34%) cases were found to be overweight with BMI in between 25 to 29.99.

30 cases (20%) found to be in obese category with BMI more than 30.

Table 3: Calculation of sensitivity, specificity, PPV and NPV of palmer's test according to BMI

	UNDERWEIGHT <18.5 (n=11)	NORMAL WEIGHT 18.5-24.9 (n=74)	OVERWEIGHT 25-29.99 (n=35)	OBESE >30 (n=30)
SENSITIVITY	0.90	0.97	0.97	0.78
SPECIFICITY	-	0.75	0.50	1
PPV	1	0.99	0.94	1
NPV	-	0.60	0.66	0.33

PPV= Positive Predictive Value NPV= Negative Predictive Value

In underweight category sensitivity, PPV values found to be .90 and 1 respectively.

In normal weight category sensitivity, specificity, PPV, NPV, were 0.97, .75, .99 and .60 respectively.

In overweight category sensitivity, specificity, PPV, NPV, were 0.97, 0.50, 0.94 and 0.66, respectively.

In obese category sensitivity, specificity, PPV, NPV were 0.78, 1, 1 and 0.33 respectively

Specificity and NPV of Palmer's test could be calculated in the underweight group as there was no true negative result.

Table 4: calculation of sensitivity, specificity, PPV and NPV of pressure profile test according to BMI

	UNDERWEIGHT <18.5 (n=11)	NORMAL WEIGHT 18.5- 24.9 (n=74)	OVERWEIGHT 25-29.99 (n=35)	OBESE >30 (n=30)
SENSITIVITY	1	0.99	1	1
SPECIFICITY	-	1	-	-
PPV	1	1	0.97	1
NPV	-	0.75	-	-

PPV= Positive Predictive Value NPV= Negative Predictive Value

In underweight category sensitivity, PPV values found to be 1 and 1 respectively.

In normal weight category sensitivity, specificity, PPV, NNV, were 0.99, 1, 1 and 0.75 respectively.

In overweight category sensitivity and PPV were 1, and 0.97 respectively.

In obese category sensitivity, PPV, were 1 and 1 respectively

Specificity in the underweight, overweight and obese groups could not be calculated as there were no true negative results.

NPV values in underweight, overweight and obese category could not be calculated due to no true or false negative results.

Table 5: Calculation of sensitivity, specificity, PPV and NPV of pressure profile test according to seniority of surgeon

	CONSULTANT	SENIOR RESIDENT	JUNIOR RESIDENT
SENSITIVITY	1	0.98	1
SPECIFICITY	-	0.66	1
PPV	1	0.98	1
NPV	-	0.66	0.5

As the table depicts sensitivity and PPV both were one in consultant group.

In case of senior residents, sensitivity, specificity, PPV and NPV were 0.98, 0.66, 0.98 and 0.66 respectively

The sensitivity, specificity, PPV all was one and NPV was 0.5 in cases performed by junior residents.

Specificity and NPV could not be calculated in consultant's group due to absence of true and false negative results.

Discussion

Laparoscopy is an important and common method of accessing the peritoneal cavity to perform many types of gynaecologic surgery. Clearly safety of entry is of the utmost importance and despite debate regarding the preferred method of achieving peritoneal access; there is no single technique with demonstrated superiority.

This prospective observational study was done to compare the two valuable safety tests namely Pressure profile test and Palmer's test in terms of sensitivity, specificity, PPV and NPV in predicting correct intra-peritoneal placement of Veress needle prior to insufflations during laparoscopic surgeries and to access the various influencing factors that can affect these tests. Total 150 consecutive patients admitted in K D Medical College, Hospital & Research Center, Mathura (UP) in June 2019 to December 2019 for different laparoscopic procedures were recruited. Various demographic data including age, BMI, history of PID, previous abdominal surgery, indication for surgery, seniority of surgeon and complications were noted prospectively.

BMI is a very important factor in relation to correct intra-peritoneal placement of Veress needle. Extremes of BMI can adversely affect the insertion of Veress needle and lead to complications. The most major technical problem in obese patients is access to peritoneal cavity, which is especially difficult with needle insertion technique. Owing to the thickness of the abdominal wall and the preperitoneal fat, accurate assessment of the location of the needle tip is difficult, making preperitoneal insufflation common. Low BMI patients have an increased risk of organ or vascular damage.

Out of 150 cases studied 11 cases were noted in underweight category, 74 in normal weight category, 35 in overweight and 30 in obese category.

In the underweight category out of 11 cases true positive results were 10 and one was found to be false negative.

In the normal body weight group out of total 74 cases true positive results were seen in 68 cases, false positive results in one, true negative in three and false negative in two.

Whereas in the overweight category of total 35 cases the numbers of true positive, false positive, true negative and false negative results were 22, 0, 3 and 6, respectively.

And in the obese category, out of 30 cases, 21 true positive, 3 true negative and 6 false negative Palmer's test results were obtained. No false positive result was obtained in the obese category.

We can see that the sensitivity of Palmer's test was 0.90 in the underweight group, 0.97 in the normal weight group, and 0.97 in the overweight group and 0.78 in the obese group.

Specificity of Palmer's test was found to be 0.75, 0.5 and 1 in the normal weight, overweight and obese group respectively.

Specificity of the Palmer's test could not be calculated in the underweight category as there was no true negative result.

The positive predictive values of Palmer's test were 1, 0.99, 0.94 and 1 in the underweight, normal weight, overweight and obese categories, respectively.

Whereas the negative predictive values of the test, as calculated, were 0.60, 0.66 and 0.50 in the normal weight, overweight and obese categories, respectively.

NPV of the Palmer's test could not be calculated in the underweight category as there were no true negative results.

All 11 cases in the underweight category and all 30 cases in the obese category showed true positive results when pressure profile test was performed.

Total 74 cases belonged to the normal body weight category, out of which, the pressure profile test showed 70 true positive, 3 true negative and 1 false negative results. No false positive result was found in the above said category.

In overweight category out of 35 cases true positive pressure profile test was found in 34 cases, while only 1 false positive result was obtained. No negative test results were obtained in this category. While in obese category, in all 30 cases, pressure profile test showed only true positive results.

Specificity of the pressure profile test could be calculated only in the normal body weight category which was one.

PPV values in underweight, normal body weight, overweight and obese categories were 1, 1, 0.97 and 1.

NPV values in underweight, overweight and obese categories could not be calculated as there was no true or false negative result.

So, we can see that the pressure profile test was more sensitive than the Palmer's test irrespective of the BMI of the patient.

Our result corresponds with the results of the studies done by Yoong et al¹⁴ in which pressure profile test was found to be more sensitive than Palmer's test across different range of BMI.

Azevedo et al in their study involving patients with BMI less than 30 found that the pressure profile test reached 100% in sensitivity, specificity, PPV and NPV.

There are few studies in literature from where we can take further references on this topic.

Very thin and extremely obese patients have higher risks of complications during laparoscopy.^{15,16} In the usual circumstances in a patient with average BMI, Veress needle is introduced through an incision at the base of the umbilicus. In obese patient with BMI >30 alternative site for Veress needle insertion can be thought. The second most common site for Veress needle insertion is the Palmer's point. Palmer's point lies 3 cm below the left costal border in the midclavicular line.¹⁷

As far as the seniority of the surgeons was concerned we divided the group of surgeons in three categories namely consultants or the visiting surgeons, senior residents and junior residents. The surgeon must have adequate training and experience in laparoscopic surgery before intending to perform any procedure independently. He

should be familiar with the equipment, instrument, energy source he intends to use. Experience of the surgeon may modify the results of the tests applied, that is why taking under consideration this fact we have included the factor of seniority of surgeon.

The consultants performed 43 cases (28.67%) out of the total 150 women recruited in the study. Out the 43 cases, the consultants found 37 true positive results, 2 true negative results and 4 false positive results when Palmer's test was performed. The sensitivity, specificity, PPV and NPV were 0.9, one, one and 0.33 respectively. Whereas out of the 56 cases (37.33%) performed by the senior residents the numbers of true positive, false positive, true negative and false negative results of Palmer's test were 48, two, three and three, respectively. The sensitivity, specificity, PPV and NPV were 0.94, 0.6, 0.96 and 0.5, respectively. The junior residents performed fifty one cases supervised by consultants. They found 44 true positive, one false positive and three each true negative and false negative results. The sensitivity, specificity, PPV and NPV of Palmer's test when performed by junior residents were 0.94, 0.75, 0.98 and 0.5 respectively.

Whereas the senior residents, out of total 56 cases performed by them, found 52 true positive, one false positive, two true negative and one false negative results. The sensitivity, specificity, PPV and NPV were 0.98, 0.66, 0.98 and 0.66, respectively.

The junior residents found fifty true positive pressure tests and one true negative result, out of total 51 cases performed by them. The sensitivity, specificity, PPV all was one and NPV was 0.5.

So we can see that pressure profile test shows higher sensitivity and PPV across all grades of surgeons as well as higher specificity and NPV.

Our study was comparable with Yoong et al¹⁴ study in which the sensitivities and specificities were consistently higher with the pressure profile test compared to palmer's test irrespective of the experience of the gynaecologists and interestingly, junior trainees had more true negatives with both tests compared to senior trainees.

Schaffer et al¹⁸ found in their study that injuries can be caused in the hands of the experienced surgeons also. They analyzed 26 major vascular injuries and reported that only four of them (15%) had been caused by inexperienced surgeons (surgeons who had performed fewer than 50 laparoscopic procedures). The other 22 injuries (85%) had been caused either by experienced surgeons (those who had performed between 51 and

100 procedures) or very experienced surgeons (over 100 procedures performed).

Researches, which are found in the literature, on the best test to reliably predict the correct intra-peritoneal placement of Veress needle are usually laboratory animal based and few studies have involved humans.¹⁹

Conclusion

So we can see that pressure profile test shows higher sensitivity and PPV across all grades of surgeons as well as higher specificity and NPV.

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