Systematic Review and Meta-analysis of Complications in Transvaginal Approach in Laparoscopic Surgery

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Abstract Transvaginal access is the most popular natural orifice transluminal technique in the minimally invasive surgery. Reviews on non-gynecological transvaginal approach morbidities reveal that rates vary greatly. A systematic review of transvaginal approach in non-gynecological intraabdominal procedures was carried out to assess the risk of complications. A systematic search was conducted using MEDLINE, EMBASE, PubMed, and the Cochrane Library from the inception of these databases to March 2012. The following keywords were searched: “transvaginal”, “NOTES”, “single incision”, and “single port”. From the total of 231 potentially eligible abstracts, 87 papers were retrieved and evaluated as fulfilling the eligibility criteria. The final analysis included 32 articles. The overall complications rate was 4.4 %, and complications related to the transvaginal port reached 2.4 %. Conversion rate to open surgery was 3.4 %. The incidence of postoperative urinary tract infection was 0.8 %. The mean operative time was 119 min. The mean hospital stay was

3.1 days (range 6 h–12 days). The technique of transvaginal access can offer several advantages for a patient and is associated with an acceptable rate of complications.

Keywords Transvaginal Surgery · Complications · Natural Orifice Transluminal Surgery · NOTES · NOSE

Introduction

Transvaginal access is nowadays the most popular natural orifice transluminal technique in the minimally invasive surgery [1]. The necessity of transaction of the vaginal fornix for the introduction of the laparoscopic port is criticized. The opponents of the transvaginal approach in non-gynecological abdominal surgery are concerned with the possibility of infection, cancer implants, sexual dysfunction, and risk of evisceration [2]. However, the data supporting these concerns are scarce.

In this systematic review, we analyzed the rate of complications following transvaginal approach in non-gynecological intraabdominal procedures.

Methods

Literature Search Strategies

A systematic search was conducted using MEDLINE, EMBASE, PubMed, and the Cochrane Library from the inception of these databases to March 2012. All papers with English abstracts were evaluated. Search terms were “transvaginal”, “NOTES”, “single incision”, and “single

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port". In addition, relevant journals were hand-searched for full-text articles and retrieved as appropriate. Overlapping search results from different databases were excluded, and one entry only was included in the final dataset.

Inclusion Criteria and Definitions

Articles were included if the English abstract contained information on the use of transvaginal access to intraabdominal surgical procedures (cholecystectomy, appendectomy, liver resection, nephrectomy, spleen resection, and colorectal resection). We included studies with both elective and emergency procedures and at least five patients participating. We defined "transvaginal approach" as the site of one of the trocars placement or site used merely for specimen extraction (hybrid technique). We excluded studies that recruited only patients with gynecological and urological procedures (with the exception of nephrectomies) as well as experimental animal studies and cadaveric studies. For the purpose of this study, we defined overall complications risk as all postoperative complications reported by the authors of the analyzed papers. Transvaginal approach-associated complications were defined as complications related directly to the use of transvaginal port (vaginal discharge, vaginal bleeding, vaginal spotting, transvaginal evisceration, and injuries occurring during introduction of transvaginal trocar).

Data Collection

All the titles and abstracts identified in the literature were screened by two authors independently (ALK, WMW). All the discrepancies were resolved by discussion.

The data were extracted by one author (JWM) and cross-checked with the remaining authors. Standard data extraction form was used for all studies.

If more than one study presented data on the same series of patients, only the most recent one was included. Complications rates were calculated as the number of patients with at least one complication over the total number of patients included in the study.

Complications rates were pooled using proportional meta-analysis. We used random-effects model to account for variability in the effect estimates [3]. The meta-analysis was performed in STATS DIRECT software.

The main results are presented in the form of forest plots. For each study, the proportions with its 95 % CI are presented. The horizontal lines represent 95 % CI and the effects estimates are presented as black squares. The sizes of those squares represent the weight that the study has in the overall effect estimate. The pooled proportion with its 95 % CI is displayed as a diamond at the bottom of the figure. For each meta-analysis, the number of studies for which results for reported outcomes were available is presented in the text.

Heterogeneity between the studies was calculated using I2 test, and it was defined as low if I2 was below 30 %, moderate if I2 was up to 50 %, and substantial if I2 was above 50 % [4].

We also investigated differences between subgroups using χ^2 test. For each type of complication endpoint, we divided studies into those with intestine and non-intestine surgery and cholecystectomy vs. not cholecystectomy surgery.

Results

Database search resulted in 208 references. Further 23 abstracts were identified, thanks to cross-referencing resulting in a total of 231 potentially eligible abstracts. One hundred and forty-five papers were excluded from the further analysis, as they were identified as follows: animal studies, cadaveric studies, transgastric and transcolonic approach, and questionnaire studies, written in languages other than English, French, Spanish, German, or Polish.

The remaining 87 papers were retrieved in full-text version and were evaluated. Two further studies were excluded because of the data overlapping with other already included publications. Fifty-two studies were excluded because they were series of less than five patients.

Thirty-two studies were included in the analysis [1, 5–35]. The flow diagram of the study is presented in Fig. 1. Basic data on all 32 papers included in this review with complications reported are presented in Table 1.

Risk of Complications (overall)

In the meta-analysis of the risk of any complication regardless of surgery type, we included 31 studies, which reported such outcome. In random-effects model, pooled risk was 4.4 % (95 % CI 3.0–6.1). Heterogeneity of the study results was low to moderate (I2 26.7 % [95 % CI 0–52.4]). The forest plot for risk of any complication is presented in Fig. 2.

Fig. 1 The flow diagram of the study

Table 1 Characteristic of the included studies

Author	Year	Patients No.	Mean (median) age/range	Type of surgical procedure	Conversions no.	Reason for conversion (type)	Complications no./Dindo score	Type of complications	Operation time (min) median/range	Discharge (days)
Solomon et al.	2012	18	No data	Appendectomy	0	–	0	–	No data	No data
Roberts et al.	2012	20	34.9/21–55	Cholecystectomy	0	–	0	–	71.4/42–116	no data
Porziglia et al.	2011	5	(58±11.9)	Nephrectomy	0	–	0	–	120/100–120	2–3
Niu et al.	2011	43	(47.2±9.6)	Cholecystectomy	0	–	0	–	88/40–190	2.7
Cuadrado-Garcia et al.	2011	25	39.7	Cholecystectomy	0	–	0	–	89.5/48–121	1
Hensel et al.	2011	80	52/19–77	Cholecystectomy	0	–	IIIb, IIIa	Urinary bladder injury, bleeding after colpotomy	47/25–80	3
Zou et al.	2011	11	43.7/33–58	Adrenalectomy	1	Injury of the spleen (open)	2× II	Emphysema, ecchymosis	102/80–310	7
Tarantino et al.	2011	40	63.4/35.4–88.2	Anterior resection	6	4× transvaginal specimen extraction impossible (open), 2× damage of Riolan anastomosis (open)	3× II	Colpotomy dehiscence, colpitis, vaginal wall ulceration	172.5/107–312	6.5
Alcraz et al.	2011	20	(49.45±8.7)	Nephrectomy	0	–	IIIb	Bleeding from uterine artery	116.47±23.8	4.1
Buesing et al.	2011	14	43/21–72	Sleeve gastrectomy	0	–	0	–	98/75–140	3
Noguera et al.	2011	10	38.25/21–42	6× cholecystectomy	0	–	0	–	86.5	2.1
				2× appendectomy	0	–	0	–	66.3	2.1
				2× peritoneal lavage and prophylactic appendectomy	0	–	0	–	55.6	2.1
Park et al.	2011	34	(61±11.2)	Right hemicolectomy	2	Transvaginal specimen extraction impossible (open)	2× I, 2× II	Ileus, urinary retention, 2× hemorrhage (transfusion)	170.8/95–300	7.9
Hackethal et al.	2010	13	51.1/30–71	Cholecystectomy, (+1 appendectomy, +1 sterilization)	1	Insufficient visibility (laparoscopy)	0	–	88.4/62–351	no data
Lehmann et al.	2010	6		Gastric sleeve resection	0	–	0	–	103.9/18–165	3.5 2 1 ±2.7
		14	62.3/35–76	Colon resection	4	4× transvaginal specimen extraction impossible (open)	0	–	122.6/55–179	12
	488		48.9/16–84	Cholecystectomy	23	22× technical problems, 1× small bowel injury (3× open, 20× laparoscopy)	3× no data, 4× IIIb, 6× II, 1× I	3× bleeding, abscess in Douglas pouch, abdominal pain (laparoscopy), 4× infection, emesis, 4× bladder injury, 2× rectum injury, small bowel injury	61.9/20–211	6.7±3.0
Salinas et al.	2010	42	36.5/17–78	Appendectomy	0	–	0	–	47.1/18–135	3.3
Alcraz et al.	2010	12	46/18–80	Cholecystectomy	1	Colon injury (laparoscopy)	IIIb, I	Wound infection, biliary leakage	147/95–220	1
Pugliese et al.	2010	14	59.1/39–78	Nephrectomy	1	Colon injury (open)	0	–	132.9/65–270	4
Linke et al.	2010	18	54/32–67	Cholecystectomy	0	–	0	–	75/40–190	2
	2010	102	52.3/18–87	Cholecystectomy	2	Technical problems (laparoscopy)	IVa, IIIb, 9× II, 4× I,	Stroke (sensorimotor hemisindrome), transumbilical hernia, 2× urinary tract infection, allergic exanthema,	62.3/25–170	3.3

Table 1 (continued)

Author	Year	Patients No.	Mean (median) age/range	Type of surgical procedure	Conversions no.	Reason for conversion (type)	Complications no./Dindo score	Type of complications	Operation time (min) median/range	Discharge (days)
Zorron et al.	2010	240	No data	Cholecystectomy	0	–	IIIa, 3× IIIb, 10× I, 1× II,	urinary retention, gastric ulcer, transient paresthesia, 2× bacterial vaginitis, vulvitis, colpomy dehiscence	96±57.8	2
		37	No data	Appendectomy	0	–	III	3× appendix vessels bleeding	60.5±31.3	1.3
		12	No data	Rectosigmoidectomy	0	–	II	Urinary tract infection	–	no data
		11	No data	Gynecologic surgery	0	–	0	–	–	no data
		5	No data	Sleeve gastrectomy	0	–	0	–	–	no data
		4	No data	Nephrectomy	0	–	IVa	Mediastinal emphysema	–	no data
		1	No data	Right colectomy	0	–	0	–	–	no data
		1	No data	Hepatic cyst	0	–	0	–	–	no data
Castro-Pérez et al.	2009	7	47.7/33–62	Cholecystectomy	0	–	0	–	72.4/61–86	1
Asakuma et al.	2009	6	No data	Cholecystectomy	0	–	0	–	116/10–160	2
Horgan et al.	2009	9	34/19–47	Cholecystectomy	0	–	0	–	114/70–165	1
Palanivelu et al.	2009	8	34.5/25–44	Cholecystectomy	2	Technical problems (laparoscopy)	2 x II, I	2× vaginal infection, bile leakage	148.5/115–182	4
Navarra et al.	2009	6	52/44–65	Cholecystectomy	0	–	0	–	52/40–65	1
Noguera et al.	2009	15	32.7/22–47	Cholecystectomy	0	–	I	Hematuria	89.62/48–121	0.5–1
DeCarli et al.	2009	12	No data	Cholecystectomy	0	–	I	1 Vulvar laceration	125.8/75–260	2
Palanivelu et al.	2008	6	29.5/25–34	Appendectomy	3	Technical problems (laparoscopy)	0	–	103.5/72–135	1–2
Ghezzi et al.	2008	33	33.4/25–43	Rectosigmoid resection	1	Inferior mesenteric artery bleeding—laparotomy (open)	IIIb, 3× I	Pelvic seroma, 3× urinary retention	290/200–390	6.7±1.8
Ramos et al.	2008	32	33/22–27	Cholecystectomy	0	–	0	–	38/18–50	0.25
Abrao et al.	2005	8	32.2/28–38	Rectosigmoid resection (infiltrating endometriosis)	0	–	0	–	177.5/119–251	4.13
Jerby et al.	1999	7	34	Proctosigmoidectomy	0	–	IIIb	1× Rectovaginal fistula	240/180–390	5–7
Redwine et al.	1996	5	No data	Rectosigmoidectomy	0	–	0	–	248/204–292	4.4

Fig. 2 Proportion meta-analysis of any complication risk in any type of surgery

Risk of Complications Related to Transvaginal Port

Complications related to the use of transvaginal port were those resulting directly from introduction of vaginal port or by the maneuvers performed through it and included the following: bladder, small intestine, or rectum injuries, vaginal discharge (bleeding, bile leak), colpitis, bleeding from the colpotomy wound, dehiscence of colpotomy, ulceration within vaginal wall, rectovaginal fistula, vulvar laceration, vaginal granuloma, dyspareunia, and subcutaneous emphysema in the perineum. Thirty studies provided data, which could be used in the meta-analysis of transvaginal approach-associated complications. Random effects model pooled risk was 2.4 % (95 % CI 1.7–3.3) with low heterogeneity (I^2 0 % [95 % CI 0–36.6]). The forest plot of risk of complications related to transvaginal port is presented in Fig. 3.

Risk of Conversion to Open Surgery

For the analysis of risk of conversion, we decided that additional trocar placements were not regarded as conversion. Random effects model meta-analysis of conversion risk in any type of surgery, which included 31 studies with such data available, showed pooled risk of 3.4 % (95 % CI 1.8–5.5). There was a moderate heterogeneity (I^2 58.7 % [95 % CI 34.2–71.4]).

Risk of Urinary Tract Infection

Thirty-two studies reported data for urinary tract infection (UTI) risk; therefore, random effects model meta-analysis of urinary tract infection risk included 32 studies. Pooled risk was 0.8 % (95 % CI 0.4–1.3) with low heterogeneity (I^2 0 % [95 % CI 0–35.7]).

Sexual Activity

Only 14 papers evaluated sexual functions after surgery. In all these papers, there was no difference in subjective evaluation of sexual functions before and after surgery. The method of evaluation of sexual activity varied between reports. The most commonly used tool to evaluate sexual activity was questionnaire provided to patient postoperatively. Unfortunately, different questionnaire types have been used despite there are validated tools for that purpose available [36]. Interestingly, in study where laparoscopic appendectomies were compared with transvaginal appendectomies, there were no significant differences in female sexual function after surgery in both groups, favoring patients after laparoscopic procedure [32].

Surgery Time

Surgery time was reported in all papers included in this review. It ranged from 38 min after transvaginal cholecystectomy to 290 min after transvaginal rectosigmoid resection with the mean operative time of 113 min [13, 28].

In-hospital Stay

Time of discharge after surgery ranged from 6 h after transvaginal cholecystectomy to 12 days after transvaginal colectomy [17, 28]. Mean hospital stay was 3.1 days.

Subgroups

We further investigated if there were differences in each analyzed outcome between subgroups defined by the type of surgery: intestinal vs. non-intestinal and cholecystectomy vs. non-cholecystectomy (Table 2). For most of the analyzed outcomes, we found no significant heterogeneity between the complications rates in the studies reporting intestinal and non-intestinal surgery. The exception was the risk of conversion, which seemed to be higher in intestinal as compared with non-intestinal surgery ($p=0.018$) as well as in non-cholecystectomy compared with cholecystectomy ($p=0.013$). However, those differences should be interpreted with caution.

Discussion

One of the dynamically developing fields in the minimally invasive surgery is the use of natural orifices as one of the routes to the peritoneal cavity. While transgastric or transcolonic approaches remain experimental, transvaginal techniques are receiving much wider attention. The transvaginal port can be either use as the sole entrance to the peritoneal cavity or as one of the various trocars used [37]. In the latter case, it can be used only for specimen extraction or as a normal working trocar. Many surgical interventions have been shown to be feasible using transvaginal access. Cholecystectomy and appendectomy are being performed in many centers [20, 24, 38]. Other, less frequently performed interventions include partial colectomy, nephrectomy, gastrectomy, hepatectomy, pancreatectomy, and gynecologic procedures [9, 25, 26, 34, 39, 40]. The potential advantages of transvaginal access to peritoneal cavity are no visible scar, faster recovery, and lower level of postoperative pain. But with the increase of the number of transvaginal operations, the concerns regarding the short-term safety of this access were raised [2].

The overall complications rate in our systematic review was 4.4 %. Other review on the same topic covering 130

Fig. 3 Proportion meta-analysis of transvaginal approach-associated risk in any type of surgery

Table 2 Subgroup meta-analysis (intestinal vs. non-intestinal and cholecystectomy vs. non-cholecystectomy) of the risk of any complication, conversion to open surgery, UTI, and complications related to transvaginal port

Subgroups	Number of studies	Random effects model risk	Heterogeneity (I^2)	p -value (χ^2 test for subgroup difference; *Fisher exact test)
Risk of any complication				
Intestinal surgery	11	5.5 % (95 % CI 2.6–9.5)	27.4 % (95 % CI 0–63.6)	0.28
Non-intestinal surgery	23	3.9 % (95 % CI 2.4–5.7)	26.4 % (95 % CI 0–55.2)	
Cholecystectomy	16	5.8 % (95 % CI 3.3–8.9)	17.6 % (95 % CI 0–54.6)	0.2
Non-cholecystectomy	18	3.5 % (95 % CI 2.0–5.4)	31.3 % (95 % CI 0–60.2)	
Risk of conversion to open surgery				
Intestinal surgery	11	6.3 % (95 % CI 2.4–12)	55.2 % (95 % CI 0–75.6)	0.018
Non-intestinal surgery	23	2.2 % (95 % CI 1.0–4.0)	46.6 % (95 % CI 1.2–66.2)	
Cholecystectomy	18	2.0 % (95 % CI 0.7–3.9)	52.8 % (95 % CI 6.2–71.2)	0.013
Non-cholecystectomy	16	5.5 % (95 % CI 2.5–9.6)	47.2 % (95 % CI 0–69.2)	
Risk of UTI				
Intestinal surgery	11	1.25 % (95 % CI 0.3–2.9)	0 % (95 % CI 0–51.2)	0.72*
Non-intestinal surgery	24	0.7 % (95 % CI 0.3–1.27)	0 % (95 % CI 0–39.6)	
Cholecystectomy	19	0.66 % (95 % CI 0.3–1.2)	0 % (95 % CI 0–42.9)	0.58
Non-cholecystectomy	16	1.4 % (95 % CI 0.5–2.9)	0 % (95 % CI 0–45.4)	
Risk of complications related to transvaginal port				
Intestinal surgery	10	2.3 % (95 % CI 0.8–4.6)	5.6 % (95 % CI 0–55.3)	0.81
Non-intestinal surgery	23	2.5 % (95 % CI 1.7–3.5)	0 % (95 % CI 0–40.2)	
Cholecystectomy	18	2.5 % (95 % CI 1.65–3.45)	0 % (95 % CI 0–43.7)	0.8
Non-cholecystectomy	15	2.5 % (95 % CI 1.1–4.4)	0 % (95 % CI 0–46.4)	

UTI urinary tract infection, CI confidence interval

patients who underwent transvaginal specimen extraction in colon surgery reported lower major complications rate of 3.7 % for left colon resections and 2 % for right colon resections [41]. In our review, we included data of 1505 patients operated on for various indications, including non-intestinal surgery, so higher risk of complications can come as a surprise. However, in our analysis, we have included both minor and major postoperative complications, which is probably the reason for the higher overall frequency. On the other hand, in a recent series of 102 transvaginal operations (72 % cholecystectomies), the risk of major complications was 3 % and of minor complications was 7 % [42]. Important differences in the reported complications rate are probably due to reporting bias. While all evaluated studies in our review seem to report all major complications, some of them fail to report minor ones. Among major intraoperative complications found in our systematic review, there were arterial bleeding and injuries to urinary bladder, small intestine, stomach wall, vaginal wall, colon, and rectum. In the postoperative period peritonitis, pelvic seroma, bile leak, rectovaginal fistula, wound dehiscence, and transient paraesthesiae were reported. There were also two cases of intraabdominal hypertension reported [34].

In our review, the conversion rate to open surgery was 3.4 %. The conversion risk for laparoscopic cholecystectomy as well as for single incision cholecystectomy was found in a

recent meta-analysis to be 0.2 % [43]. The much higher conversion rate found in this review can reflect the technically challenging intraoperative situation and also the fact that surgeons performing transvaginal approach decided to stay rather on the “safe side” of this relatively new technique.

In our review, all complications related to the transvaginal port reached 2.4 %. These complications included vaginal discharge (bleeding and bile leak), colpitis, dehiscence of colpotomy, ulceration within vaginal wall, rectovaginal fistula, vulvar laceration, vaginal granuloma, dyspareunia, and subcutaneous emphysema in the perineum. It included also all injuries to other organs occurring during introduction or intraoperative usage of the vaginal port.

It seems that the higher risk of conversion to open surgery may be associated with intestinal vs. non-intestinal surgery (6.3 % vs. 2.2 %; $p=0.018$) and with non-cholecystectomy vs. cholecystectomy (5.5 % vs. 2.0 %; $p=0.013$). No differences in the overall risk of complications between intestinal vs. non-intestinal and cholecystectomy vs. non-cholecystectomy were found. The differences in the risk of UTI and complications related to transvaginal port between the same groups were also of no statistical importance. However, those results should be interpreted with caution since the observed differences may be a result of chance or the difference in reporting of complication between the studies as no standard of reporting exists for case series.

The proximity of transvaginal port to the urinary catheter can result in urinary tract infections. The incidence of postoperative urinary tract infection in our review was 0.8 %. However, in the subpopulation of rectosigmoid resections in the multicenter study by Zorron, the frequency of UTI was elevated to 8 % [34]. Indeed, in the same subpopulation in our review, the rate of UTI was 4.5 %. The real incidence of UTI can be even higher as some papers failed to report this relatively minor complication. Apart from the type of surgery, also longer surgery time can lead to the increased postoperative urinary tract infections. The mean operative time of 119 min for transvaginal procedures can also be a factor for the rise in the UTI incidence.

One of the possible complications of transvaginal access is intestinal evisceration through vaginal roof opening. Although it has been described in the literature in patients undergoing gynecologic procedures, we have not seen this complication in our review [44].

Conclusion

The technique of transvaginal access can offer several advantages for a patient and is associated with an acceptable rate of complications: the overall complications rate was 4.4 % and complications related to the transvaginal port reached 2.4 %.

Conflict of interest statement None declared.

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