Is There An Optimal Technique For

Laparoscopic Vesicovaginal Fistula Repair?

: A Systematic Review

John R Miklos MD, Robert D Moore DO, and Orawee Chinthakanan, MD, MPH

International Urogynecology Associates

Atlanta GA and Beverly Hills CA

Corresponding Author John R Miklos MD 3400 Old Milton Parkway C330 Alpharetta, Georgia 30005 JRM@miklosandmoore.com

Author Contribution:

JRM: Protocol/Project development, Data collection, Data analysis, Manuscript writing,

Manuscript revision

RDM: Protocol/Project development, Data collection

OC: Search strategy, Data collection, Data analysis, Manuscript writing

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Abstract:

Introduction and objective: Two types of laparoscopic vesicovaginal fistula (VVF) repairs, the traditional transvesical (O'Conor) and extravesical techniques, dominate the literature. We present a systematic review of success rate compared between transvesical and extravesical laparoscopic techniques in VVF patients.

Data Sources: Eligible studies, published between 1994 and March 10, 2014, were retrieved through Medline and bibliography searches.

Method of Studies Selection: To 1) review the literature on laparoscopic (including robotic assisted) surgery in the treatment of VVF 2) compare and contrast the extravesical technique to the traditional transvesical O'Conor technique 3) review the success of laparoscopic VVF repair based on layers of fistula closure 4) review the potential necessity of omental flaps during laparoscopic VVF repair and 5) discuss conventional criteria for a good VVF. For spectrum of adverse events, all study designs were included.

Tabulation, Integration and Results: Only one retrospective cohort study was included with the remaining articles made up of case reports and case series. 44 studies were included in a systematic review. There were 9 articles of robotic-assisted approach, 3 laparoscopic single-site surgery (LESS), and 31 conventional laparoscopic approach. A literature review reveals a balanced number of reports for both transvesical and extravesical approaches. Statistical meta-analysis was not performed due to high heterogeneity. The overall success rate of laparoscopic VVF repair was 80- 100% with follow-up period 1- 74 months.

Conclusion: Transperitoneal extravesical VVF repairs do not appear to have existed in the literature prior to the first laparoscopic VVF and since its introduction it has cure rates similar to the traditional transvesical approach. Laparoscopic extravesical VVF repair is a safe, effective, minimally invasive technique with excellent cure rates similar to those of the conventional transvesical approach in experienced surgeons hands. **Keywords**: Bladder fistula; Laparoscopic vesicovaginal fistula repair; O'Conor; Omental flap; Vesicouterine fistula; Vesicovaginal fistula Laparoscopic extravesical VVF repair is a safe, effective and less invasive alternative to the O'Conor technique with excellent cure rates.

INTRODUCTION

The success of vesicovaginal fistulas (VVF) repair depends on various factors, including fistula size, location, timing from the antecedent event, severity of symptoms, quality of surrounding tissue, and clinical experience and surgical skill^{1,2}. Surgical repairs of VVF are most commonly performed: 1) vaginally 2) abdominally and 3) laparoscopically with and without robotic assistance. The approach to VVF repair is often dictated by surgeons' preference, location or complexity of the VVF². Surgeon's preference is usually based on his/her training and experience. Laparoscopic/robotic VVF approaches reveal the most commonly performed techniques are: the traditional O'Conor transvesical technique and the more recent less known extravesical technique. The O'Conor technique³ was first described in the 1970's and requires a bladder bivalving technique or cystotomy to identify and repair the VVF (Figure 1), the extravesical technique was first described in the late 1990's ^{4,5} and is performed by focusing on a site specific dissection (Figure 2) and repair technique without cystotomy or bivalving of the bladder.

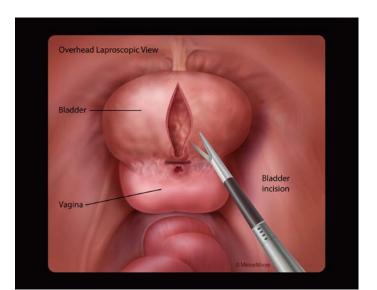
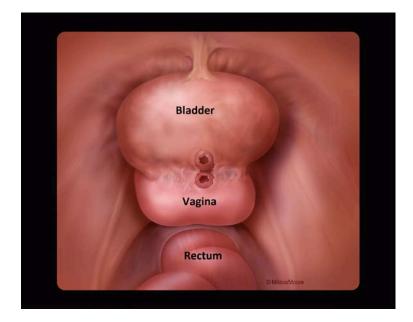


Figure 1 – O'Conor transvesical approach

Figure 2 - Extravesical approach



Though there are distinct differences in the two techniques, the literature is unclear and often does not acknowledge the difference and lumping the two laparoscopic techniques together⁶⁻⁸, claiming all techniques are "a variation of the O'Conor technique"^{9,10} or making claims the laparoscopic extravesical technique is a "novel" technique¹¹, despite appearing in the literature since the 1990's^{4,5,12}. Not only has there been a lack of clarity in the literature distinguishing the two techniques but there has been little to suggest standardization let alone equality or superiority of either technique. In fact randomized controlled trials are lacking to help determine superiority. The majority of articles published review outcomes of case reports and case series with no standardized approaches to outcomes and follow-up the comparison of methods of VVF is difficult.

The goal of this systematic review is to 1) review the literature on laparoscopic (including robotic assisted) surgery in the treatment of VVF 2) compare and contrast the extravesical technique to the traditional transvesical O'Conor technique 3) review the

success of laparoscopic VVF repair based on layers of fistula closure 4) review the potential necessity of omental flaps during laparoscopic VVF repair and 5) discuss conventional criteria for a good VVF.

METHODS

Protocol and registration

Methods of analysis and inclusion criteria were specified in advance and documented in a protocol.

Eligibility Criteria

We included randomized controlled trail, cohort, cross-sectional, case report of laparoscopic VVF repair in VVF women, with or without synthetic mesh. Participants of any age with VVF women who underwent surgery were considered. Vesicovaginal fistula (VVF) defined as an abnormal fistulous tract extending between the bladder and vagina resulting in the continuous, involuntary discharge of urine into the vagina. This review was limited to studies looking at laparoscopic and robotic-assisted approaches, not included open laparotomy and vaginal approaches. The primary outcome measures post-operative cure rate. Extra- vs. transvesical techniques, flap vs. non-flap, and number of layers of fistula closure were determined. We collected follow-up period, operative time, length of hospital stay, and postoperative complications.

Information sources

We searched Medline with English language restrictions from 1994 to March 2014. Additional eligible studies were sought by a hand search of reference lists from primary articles and relevant reviews. We conducted our searches on March 10, 2014 and applied English language restriction. We also included our study of 44 patients undergoing laparoscopic VVF repair that has been recently accepted for publication¹³.

<u>Search</u>

We used the following search strategy to search all databases: laparoscopy; vesicovaginal fistula; robotic (Table 1). We restricted the database from January 1994 to March 10, 2014.

Table 1- PubMed Search strategy

((((("laparoscopy"[MeSH Terms] OR "laparoscopy"[All Fields] OR "laparoscopic"[All Fields]) AND ("vesicovaginal fistula"[MeSH Terms] OR ("vesicovaginal"[All Fields] AND "fistula"[All Fields]) OR "vesicovaginal fistula"[All Fields])) OR (("robotics"[MeSH Terms] OR "robotics" [All Fields] OR "robotic" [All Fields]) AND ("vesicovaginal fistula" [MeSH Terms] OR ("vesicovaginal"[All Fields] AND "fistula"[All Fields]) OR "vesicovaginal fistula"[All Fields]))) AND ("vesicovaginal fistula"[MeSH Terms] OR ("vesicovaginal"[All Fields] AND "fistula"[All Fields]) OR "vesicovaginal fistula"[All Fields])) OR (("laparoscopy"[MeSH Terms] OR "laparoscopy"[All Fields] OR "laparoscopic"[All Fields]) AND ("vesicovaginal fistula"[MeSH Terms] OR ("vesicovaginal"[All Fields] AND "fistula"[All Fields]) OR "vesicovaginal fistula"[All Fields]) AND ("surgery"[Subheading] OR "surgery"[All Fields] OR "surgical procedures, operative"[MeSH Terms] OR ("surgical"[All Fields] AND "procedures"[All Fields] AND "operative"[All Fields]) OR "operative surgical procedures" [All Fields] OR "surgery" [All Fields] OR "general surgery"[MeSH Terms] OR ("general"[All Fields] AND "surgery"[All Fields]) OR "general surgery"[All Fields]))) AND (("1994/01/01"[PDAT] : "2014/12/31"[PDAT]) AND English[lang])

Study selection

Two reviewers (JRM and OC) independently screened titles and abstracts, and the reviewed the full text of potentially relevant articles. Disagreements between reviewers were resolved through discussion.

Data collection process

We developed a data extraction sheet and refined it accordingly. One reviewer author (OC) extracted the following data from included studies and the second author checked the extracted data (JRM). We resolved disagreements through discussion between the two review authors.

Data items

Information was extracted from each included trail on: (1) characteristics of trial participants (including number of patients, etiology of VVF, prior VVF repair, robotic or laparoscopic approaches, operative time, estimated blood loss, length of hospital stay, follow-up time, and complications), and the trail's inclusion and exclusion criteria; (2) type of intervention (including transvesical vs. extravesical technique, number of bladder closure, number of vaginal closure, interposition, bladder test, and bladder dye test); (3) type of outcome measure (cure rate at the follow up time). Cure was defined as no urinary leakages from the vagina at post op follow up. Cure rate of VVF repair was the primary measure of treatment effect.

For the studies included, we have assessed results reported including the possible author biases and patient attrition. Data was analyzed using SAS (version9.3, SAS Institute Inc, Cary, NC) statistical software.

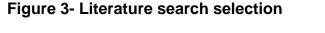
RESULTS:

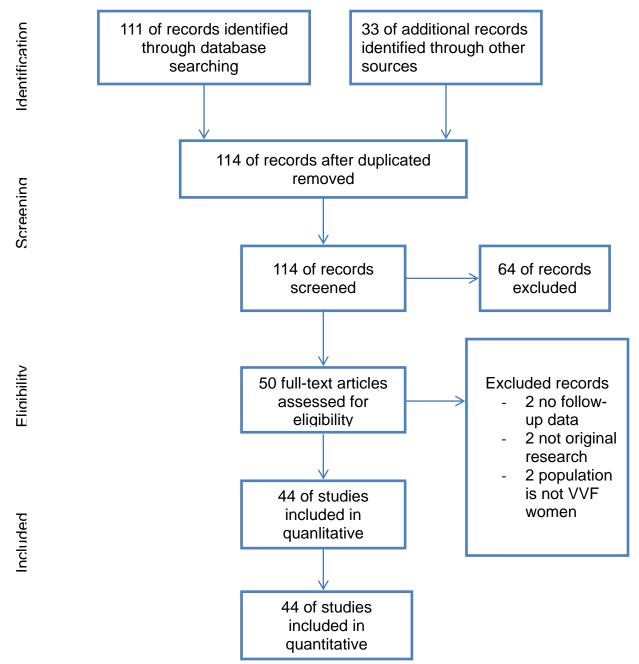
Included Studies

Our searches yielded 114 citations, of which we reviewed the full text of 50; 44 met all inclusion criteria (Figure 3). Study quality assessment to detect selection, performance, attrition, detection bias, and conflict of interest were conducted. In the majority of the studies, there was no comparison of laparoscopic VVF repair with other VVF repair procedures, with only one study having comparison between open and robotic-assisted VVF repair. The majority of studies were observational case report and case series with similar objective outcome. All 44 studies defined no evidence of continuous urinary leakage from vagina as the objective outcome of success.

Overall, 44 articles were fulfilling the inclusion criteria that accounting for 256 patients (Table 2). There were 9 articles of robotic-assisted approach, 3 laparoscopic single-site surgery (LESS), and 31 conventional laparoscopic approaches. Table 3 describes study characteristics. Most of the population in the study was in their forties (range 16 -72 years). The most common cause of VVF was hysterectomy. Most of patients underwent primary VVF repair with interval from previous surgery \geq 12 weeks. There were 19 studies utilized extravesical technique (n=103), 22 studies of transvesical (conventional) O'conor technique (n=146), and one study that described using both techniques. Duration of follow-up ranged from 1- 74 months. There are 16 studies that had primary outcome follow up \geq 12 months. The overall success rate of laparoscopic VVF repair across all studies was 80-100%. The success rate of extravesical and transvesical technique were 97.67%- 100% and 80- 100% respectively. The success rate of single and double layers of bladder closure was 80-100% and 93.33-100% respectively. Comparing between interposition flap vs. no flap, the success rate of

interposition flap, including omental, peritoneal, fibrin glue and fleece-bound sealing system, was 80- 100% from 35 studies. Six studies that patients did not received interposition grafts reported 97.67- 100% success rate.





Retrograde bladder filling to test the integrity of the suture line was described in 47.73% (21/44) of studies with 23.81% (6/21) of the studies revealing a retrograde fill of 200cc or less, 38.10% (8/12) describing 250 cc. or more and 33.33% (7/21) not mentioning the amount of fluid utilized. Patients receiving bladder fills less than or equal to 200cc had an overall success rate 100%, those receiving bladder fills of 250cc or more had an overall success rate 97.67-100%. Patients undergoing a bladder fill and integrity test at any volume had a VVF cure rate of 97.67-100% Patients not receiving a retrograde bladder fill after VVF repair had a cure rate of 80-100%.

For the number of repair layers utilized for VVF repair, all studies revealed a standard technique for their patients with each study detailing between 1-4 layers of repair. Approximately 61.34% (146/238) of patients had single layer bladder repair and 38.66% (92/238) were reported to have double-layer bladder closure. For vaginal closure, 6.72% (16/238) had no vaginal closure, 81.93 (195/238) had single layer closure, and 11.34% (27/238) had double layers closure (Table 4).

Author, year	N	Type of Stud y	Study period	Age (range)	Etiol ogy	Prior repair	Timin g of repair	Appr oach	Trans vesica I vs. Extrav esical	#BI add er clos ure laye rs	#Vag inal Clos ure layer s	Interp ositio n	Blad der test (cc)	Blad der testi ng dye	OR time (minutes)	EBL (cc)	Leng th of Stay* (day s)	Drain age time (day s)	Cure Rate (%)	Averag e F/U* (month s)	Compli cations
Miklos & Moore, 2014 ¹³	44	Case serie s	1998- 2014	46.5 (31- 72)	Hyst erect omy (41), Mes h (2), spon tatne ous (1)	11 patie nts - Vagi nal (12), Abd omin al (4)- 3 w/o ment um	N/A	Conv entio nal	Extrav esical	2	1	None	300- 400	Inidg o carmi ne	N/A	39 (0- 450)	1.1 (1-3)	14-21	43/44 (97.7 3%)	17.3 (3- 64)	None
Dutto and O'Reilly, 2013 ¹⁴	1	Video case repor t	N/A	56	ТАН	Non e	N/A	Robo tic	Extrav esical	2	2	Oment al	No	No	N/A	N/A	2	10	1/1 (100 %)	6	None
Nagabhus hana et al, 2013 ¹⁵	1	Case repor t	March- Novem ber 2012	28	N/A	N/A	N/A	LESS	N/A	N/A	N/A	N/A	N/A	N/A	180	N/A	3	14	1/1 (100 %)	N/A	Wound infectio n
Garcia- Segui, 2012 ¹⁶	4	Case serie s		42 (38– 47)	Hyst erect omy (4)	None		Conv entio nal	Extrav esical						160(120- 186)			21	4/4 (100 %)		None
Kurz et al, 2012 ¹⁷	3	Case serie s	N/A	40-64	TAH (3)	None	Immed iate	Robo tic	Extrav esical	1	1	Perito neal	Yes (N/A)	No	N/A	N/A	5	14	3/3 (100 %)	42	None
Miklos & Moore, 2012 ¹⁸	1	Case repor t	N/A	52	ТАН	Twice (at the time of TAH abdo minal with oment	20 weeks	Conv entio nal	Extrav esical	2	1	None	400	Inidig o carmi ne	N/A	N/A	N/A	14	1/1 (100 %)	24	None

 Table 2- Summary of included studies evaluating the laparoscopic VVF repair

						al flap)															
Miklos & Moore, 2012 ¹⁹	1	Case repor t	N/A	37	ТАН	3 times (2 Latzk o, fibrin glue)	12 weeks	Conv entio nal	Extrav esical	2	1	None	400	Inidig o carmi ne	N/A	N/A	N/A	14	1/1 (100 %)	24	None
Rogers et al, 2012 ²⁰	2	Case repor	N/A	42 and 51	TAH (2)	None	N/A	Robo tic	Transv esical	1	2	Oment al	No	No	N/A	N/A	2	10-14	2/2 (100 %)	12	None
Roslan et al, 2012 ²¹	1	Case repor t	August 2011	72	ТАН	None	12 weeks	LESS	Transv esical	1	1	None	200	No	170	Minim al	5	14	9/9 (100 %)	6	None
Simforoos h et al, 2012 ²²	5	Case serie s	August 2010- Decem ber 2011	45.6 (44-48)	TAH (4), Radi cal Hyst erect omy (1)	None	Immed iate to 3 weeks	Conv entio nal	Transv esical	1	1	Oment al (4), none (1)	No	No	134 (100- 185)	300 (250- 370)	4 (3-6)	14	4/5 (80%)	8 (2-15)	None
Sirithanap hol et al,2012 ²³	5	Case serie s	October 2008- Decem ber 2010	42 (33- 53)	TÁH (4), C/S (1)	None	≥20 weeks	Conv entio nal	Transv esical	N/A	N/A	Oment al	No	No	229 (150- 300)	66 (30- 100)	4.4 (4-6)	18-34	5/5 (100 %)	24.4 days (28-34 days)	None
Utrera et al, 2012 ²⁴	9	Case serie s	January 2006- January 2008	45±13	TAH (9)	None (8), Trans vagin al (1)	88 weeks	Conv entio nal	Transv esical	1	1	Oment al	200	No	150	N/A	4.7	10	1/1 (100 %)	32	UTI (1)
Zhang et al, 2012 ²⁵	18	Case serie s	Novem ber 2007- October 2011	37.6 (27-51)	TAH (16), Ob trau ma (2)	None	Immed iate	Conv entio nal	Transv esical	1	2	Oment al	Yes (N/A)	No	135 (75- 175)	95 (50- 200)	5 (4- 7)	14	18/18 (100 %)	22.7 (3- 45)	None
Abdel- Karim et al, 2011 ²⁶	5	Case serie s	N/A	47±4	TÁH (4),C /S (1)	None	≥12 weeks	LESS	Extrav esical	2	1	Oment al	250	No	198±27.7	90±25	2	21	5/5 (100 %)	8 (4-12)	None
Abdel- Karim et al, 2011 ²⁷	15	Case serie s	N/A	35.2±9 .5	TAH (6), C/S (5), Ob trau ma	None	≥12 weeks	Conv entio nal	Extrav esical	1	1	Oment al	300	No	172 (145- 210)	110±1 7	3 (2- 5)	21	15/15 (100 %)	19	None

					(3), Myo mect omy (1)																
Gupta et al, 2010 ²⁸	12 vs. 20 op en	Retro spect ive cohor t	August 2006- June 2008	27.1 (16-46)	Obst ructe d labor (6), hyst erect omy (4), C/S (2)	Abdo minin al (8), vagin al (4)	24 weeks (12- 56)	Robo tic vs. open	Transv esical	1	1	Oment al, periton eal, or epiploi c appen dices of the sigmoi d colon	No	No	140 (110- 180)	88 950- 200)	3.1 (2-5)	14- 21	12/12 (100 %) vs. 90% (open)	N/A	None
Lee et al, 2010 ²⁹	5	Case serie s	October 2007- March 2009	47 (40- 51)	TAH (5)	None	24 (14- 289) days	Conv entio nal	Extrav esical	2	1	None	250	No	95 (85- 115)	N/A	5(5- 17)	14	5/5 (100 %)	56.1 (26.6- 74)	None
Rizvi et al, 2010 ³⁰	8	Case serie s	2004- 2008	36 (24- 49)	Hyst erect omy (5), C/S (3)	2 patien ts - (Abdo minal & Vagin al), Abdo minal	14 (8- 32) weeks	Conv entio nal	Transv esical	1	1	Oment al	75	No	145 (110- 160)	60 (40- 100)	4	14	8/8 (100 %)	29 (5- 50)	None
Gozen et al, 2009 ³¹	3	Case serie s	N/A	34-48	Hyst erect omy (3)	None	≥12 weeks	Conv entin al	Transv esical	1	1	Perito neal	300	No	164 (141- 195)	333 (250- 400)	6	10	3/3 (100 %)	20 (14- 30)	None
Gregorio et al, 2009 ³²	1	Case repor t	N/A	50	ТАН	None	32 weeks	Conv entio nal	Transv esical	N/A	N/A	Perire ctal fat	No	No	210	N/A	8	15	1/1 (100 %)	18	None
Porpoglia et al, 2009 ³³	4	Case serie s	January 2007- July 2008	43-60	Hyst erect omy (4)	None	N/A	Conv entio nal	Transv esical	2	1	Oment al	Yes (N/A)	No	103 (95- 120)	80 (50- 100)	3 (2- 4)	8	4/4 (100 %)	14.5 (10-21)	None
Shah, 2009 ³⁴	25	Case serie s	June 2003- Novem ber 2008	N/A	hyst erect omy (16), Obst etric trau ma	None	≥2 weeks	Conv entio nal	Transv esical	1	1	Oment al	No	No	145	180- 200	4.5	14	19/22 (86.3 6%)	N/A	Conver sion due to dense adhesio n (3)

					(9)																
Abreau et al, 2008 ³⁵	8	Case serie s	N/A	N/A	TAH (7), Uret erolit hotri psy (1)	Abdo minal (2), vagin al (1), endos copic fulgur ation (1)	N/A	Conv entio nal	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	7/8 (87.5 %)	N/A	Lower limb compart ment syndro me (1), 1 convers ion
Erdogru et al, 2008 ³⁶	1	Case repor t	N/A	37	Cesa rean- Hyst erect omy	1 patien t- (Abdo minal & Trans vagin al)	40 weeks	Conv entio nal	Transv esical	1	1	Fleece -bound sealin g syste m	Yes (N/A)	No	185	50	3	21	1/1 (100 %)	6	None
Hemal et al, 2008 ³⁷	7	Case serie s	August 2006- October 2007	N/A	Hyst erect omy (3), Ob trau ma (4)	Trans abdo minal (8), Trans vagin al (5)	≥12 weeks	Robo tic	Transv esical	2	1	Oment al	Yes (N/A)	No	141 (110-160)	90	3 (2- 4)	14	7/7 (100 %)	12	None
Otsuka et al, 2008 ³⁸	7	Case serie s	Febuary 2004- March 2006	52.8 (37- 74)	Hyst erect omy (6), Endo metri osis surg ery(1)	3 patien ts- Abdo minal (2), Endo scopi c fulgur ation(1)	≥28 weeks	Conv entio nal	Transv esical (5) Extrav esical (2)	1	1	Oment al	No	No	280 (130- 420)	N/A	7.2 (2- 20)	28	7/7 (100 %)	11(2- 24)	UTI (1), Compar tment syndro me (1)
Das Mahapatra & Bhattachar yya, 2007 ³⁹	11	Case ⁱ serie s	1991- 2004	N/A	TAH (7), Obst etric trau ma (4)	None	≥12 weeks	Conv entio nal	Extrav esical	1	0	Omnet al	No	Yes (N/A)	192 (180- 222)	125	(4- 14)	14	10/11 (90.9 1%)	>3	None
Nagraj et al, 2007 ⁴⁰	12	Case serie	Febuary 2001-	37.2 (20-55)	TAH (13)	None	≥2 weeks	Conv entio	Transv esical	1	1	Oment al	No	No	130 (110- 160)	N/A	4.5 (3-7)	15 (14-	11/12 (91.6	21 (6- 36)	Laparot omy (1)

		S	Novem					nal										16)	7%)		
			ber 2005																		
Tiong et al, 2007 ⁴¹	1	Case repor t	N/A	44	TAH (1)	None	12 weeks	Conv entio nal	Extrav esical	1	1	Oment al	150	No	260	100	1	21	1/1 (100 %)	6	None
Schimpf et al, 2007 ⁴²	1	Case repor t	N/A	41	TAH	None		Robo tic	Extrav esical	2	1	Oment al	No	No	245	N/A	1	N/A	1/1 (100 %)	3	None
Sears et al, 2007 ⁴³	1	Case repor t	N/A	47	TAH	None	3 years	Robo tic	Extrav esical	2	1	Oment al	No	No	N/A	N/A	N/A	N/A	1/1 (100 %)	N/A	None
Modi et al, 2006 ⁴⁴	1	Case repor t	N/A	38	TVH	None	10 weeks	Conv entio nal	Transv esical	1	2	Oment al	Yes (N/A)	No	170	50	2	14	1/1 (100 %)	3	None
Patankar et al, 2006 ⁴⁵	1	Case repor t	N/A	52	Hyst erect omy	None	12 weeks	Conv entio nal	Extrav esical	1	1	None	No	No	155	60	3	14	1/1 (100 %)`	9	None
Sundaram et al, 2006 ⁴⁶	5	Case serie s	N/A	N/A	Hyst erect omy (4), myo mect omy (1)	None	≥12 weeks	Robo tic	Transv esical	2	2	Oment al	200	Povid one- iodin e	233 (150-330)	70	5 (4- 7)	10	5/5 (100 %)	6	None
Wong et al, 2006 ⁴⁷	2	Case serie s	N/A	N/A	TÁH(1), Cesa rean- Hyst erect omy(1)	2 patien ts - Trans vagin al (2)		Conv entio nal	Transv esical	1	1	Oment al	No	No	347(262- 432)	<100	2	21	2/2 (100 %)	40 (39- 41)	None
Chibber et al, 2005 ⁴⁸	6	Case serie s	January 2000- April200 4	N/A	TAH(6)	2 patien ts- Trans vagin al (2)	≥6 weeks	Conv entio nal	Transv esical	1	1	Oment al	No	No	220 (190- 280)	N/A	3	21	6/6 (100 %)	3-40	None
Melamud et al, 2005 ⁴⁹	1	Case repor t	N/A	44	TVH	None	N/A	Robo tic	Transv esical	2	1	Fibrin glue	Yes (N/A)	Indig o carmi ne	280	50	3	14	1/1 (100 %)	4	None
Sotelo et al, 2005 ⁵⁰	15	Case serie s	August 1998- March 2004	N/A	Hyst erect omy (14), Obst erics	4 patien ts- Abdo minal(3),	≥8 weeks	Conv entio nal	Transv esical	2	1	Oment al	No	No	170 (140- 240)	N/A	3 (2- 5)	10.4 (9- 15)	14/15 (93.3 3%)	26.2 (3- 60)	Enterot omy (1), Enteroc utaneou s fistula (1),

					trau ma (1)	Trans vagin al (1)															Epigastr ic artery injury (1)
Ou et al, 2004 ⁵¹	2	Case serie s	June 1994- Septem ber 2002	N/A	Hyst erect omy (2)	None	≥4 weeks	Conv entio nal	Extrav esical	2	0	Oment al	No	No	N/A	N/A	2-12	14-20	2/2 (100 %)	N/A	None
Nabi et al, 2001 ⁵²	1	Case repor t	N/A	40	TVH	Trans vagin al (1)	10 month s	Conv entio nal	Extrav esical	1	1	Oment al	200	Povid one- iodin e	190	N/A	4	21	1/1 (100 %)	9	None
Miklos et al, 1999 ⁵³	1	Case repor t	N/A	36	TAH (1)	Trans vagin al (2)	10 weeks	Conv entio nal	Extrav esical	1	1	Oment al	300	No	N/A	<50	N/A	21	1/1 (100 %)	6	None
von Theobold et al, 1998 ⁵⁴	1	Case repor t	N/A	49	TAH (1)	None	16 weeks	Conv entio nal	Extrav esical	1	0	Oment al	No	Meth ylene blue	70	<100	8	7	1/1 (100 %)	6	None
Phipps, 1996 ⁵⁵	2	Case serie s	N/A	35, 49	Hyst erect omy (2)	None	6, 8 weeks	Conv entio nal	Extrav esical	1	0	Oment al	No	No	160	N/A	8	10	2/2 (100 %)	3-6	None
Nezhat et al, 1994 ⁵⁶	1	Case repor t	N/A	45	Endo metri osis surg ery	None	12 weeks	Conv entio nal	Transv esical	1	1	Perito neal	No	No	85	100	1	10	1/1 (100 %)	10	None

	No./Total (%) of Patients
Age (years)	16- 72*
Etiology of VVF	
- hysterectomy, radical hysterectomy	210/260 (80.77)
- OB trauma	43/260 (16.54)
- etc e.g. endometriotic resection, mesh,	7/260 (2.69)
myomectomy, urethrolithotripsy	
Interval from index surgery	Immediate- 88 weeks
Approach	
- Conventional	217/257 (81.32)
- LESS	7/257 (27.24)
- Robotic	33/237 (12.84)
Technique**	
- Transvesical	146/248 (58.87)
- Extravesical	102/248 (41.13)
Bladder closure layers**	, , , , , , , , , , , , , , , , , , ,
- Single	146/238 (61.34)
- Double	92/238 (38.66)
Vagina closure layers**	
- None	16/238 (6.72)
- Single	195/238 (81.93)
- Double	27/238 (11.34)
Interposition***	
- None	53/244 (21.72)
- Omental	182/244 (74.59́)
- etc. i.e. peritoneal, fleec-bound system	9/244 (3.69)
Bladder test***	134/244 (54.92)
Bladder testing dye***	64/244 (26.23)
Operative time (min.)	70-432
Estimated blood loss (cc.)	0-450
Length of hospital stay (days)	1-20
Drainage time (days)	7-28
Follow-up period (months)	1-20
Postoperative complications	
- Conversion	5/260
- UTI	2/260
- Wound infection	1/260
- Enterotomy	1/260
- Enterocutaneous fistula	1/260
- Compartment syndrome	2/260

 Table 3- Patient Characteristics pooling data (n=260)

missing data=19 *missing data=13

	Success rate	RR (95% CI)
Overall	248/257 (96.50)	
Technique		
- Transvesical	140/146 (95.89)	0.98 (0.94- 1.02)
- Extravesical	100/102 (98.04)	
Bladder layer closure		
- Single	140/146 (95.89)	0.98 (0.94- 1.03)
- Double	90/92 (97.83)	
Vaginal layer closure		
- None	15/16 (93.75)	0.97 (0.85- 1.11)
- Single	188/195 (96.41)	Ref.
- Double	27/27 (100)	0.94 (0.83- 1.06)
Interposition		
- Omental, peritoneal, etc.	184/191 (96.34)	0.98 (0.94- 1.03)
- None	52/53 (98.11)	
Bladder test		
- Yes	133/134 (99.25)	1.06 (1.01- 1.12)
- No	103/110 (93.64)	
Bladder testing dye		
- Yes	62/64 (96.88)	1.01 (0.95-1.06)
- No	174/180 (96.67)	

Table 4- Success rate of laparoscopic VVF repair from pooling data (n=260)

DISCUSSION:

The O'Conor transvesical technique was performed via laparotomy for more than 30 years before the first laparoscopic case was published in 1994⁵⁶. It wasn't until 1998 von Theobold described the first laparoscopic extravesical VVF repair⁴. Von Theobold describes a simple dissection of the bladder away from the vagina and a single-layer bladder closure as "closure of the vagina was not necessary" coupled with an omental J flap. A novel and unorthodox approach (i.e. a single layer closure) yet successful in this single case study. A few months later, Miklos et al³ described a laparoscopic extravesical technique utilizing a three layer closure, double layer bladder and a single layer vagina closure, with an intervening omental flap for a patient with recurrent fistula despite two Latzko procedures. Since then 44 papers and case studies on laparoscopic/robotic assisted laparoscopic VVF repairs have been published. A review of these papers reveals an almost equal distribution of papers written on both the

laparoscopic transvesical and extravesical techniques. However there do not appear to be any papers in the literature describing an extravesical technique via laparotomy.

Despite the fact that half of these papers describe an extravesical approach, rarely are both procedures discussed in the same paper making it difficult to understand the difference between the two procedures. Until recently^{34,38,57} most VVF publications and reviews either don't acknowledge or distinguish the difference between the two techniques, transvesical (O'Conor) and extravesical. In fact some experts have implicated that the extravesical technique is a modification of the O'Conor technique^{9,10}. This extravesical approach is not a modification of the O'Conor technique as a cystotomy is not required to identify the fistula repair, but it still uses the basic principles of fistula repair as cited by Couvelaire in the 1950's⁵⁸.

Logically the extravesical technique is a less invasive and less traumatic dissection than than the bivalving O'Conor technique. The extravesical VVF site – specific dissection and layered closure technique discussed herein, one minimizes the bladder defect by not performing a cystotomy. Bivalving, increases the size of the bladder defects and, in theory, increases the chance of failure of the VVF repair. A large incision in the bladder, to identify the fistula tract, has never been proven to increase the success of VVF repair. These theories can be supported by fistula experts who: 1) have stated there is a greater chance of surgical failure with larger fistulas⁵⁸ 2) attempt to minimize the size of the cystotomy (<2 cm) at the time of an O'Conor technique³⁰ and 3) have reported great success using the non bivalving extravesical layered-closure technique with and without omental flaps.

It is often said there are a number of things that may affect the success of fistula repair, including: number of previous surgical attempts; patients health status; surgeon's experience⁵⁹, fistula size⁶⁰, fibroisis⁶¹, and radiation exposure⁶². Probably

even more important to a successful VVF repair are the technical steps of the surgery. Conventional wisdom suggests that the criteria for a good repair includes: "good visualization, good dissection, good approximation of the margins, tension-free watertight closure, use of a well vascularized tissue flaps and adequate post operative urinary drainage⁶³. Others believe that it is essential to place an interposition graft in an attempt to achieve the highest possible cure rate^{58,64,65}. Though each of these principles sound logical and pragmatic for a successful VVF repair they are based on supposition and little science.

The authors agree that "good visualization, good dissection, good approximation of the margins" are important but they are hallmark criteria of any *good* surgery. They also agree, as with any surgery, tissue repair should not be overly stressed or tensioned post operatively as it could lead to a wound disruption or dehiscence. This is the role of a good dissection and mobilization of the vagina and bladder tissue prior to suturing their defects as well as adequate bladder decompression post VVF repair. Obviously excessive bladder volumes could stress the suture line and instigate a bladder wound dehiscence. However the need for 1) an interposition flap and 2) what constitute a good approximation & tension-free watertight closure are suspect.

The literature has always been suggestive of higher cure rates with the use interposition grafts during VVF repairs, however definitive proof does not exist. Most recently the use of interposition flaps has been questioned in non-irradiated patients^{1,13,66}. In 2013 a retrospective review of 49 patients without malignancy or a history of radiation therapy the primary surgeon determined that transvaginal repair of benign, recurrent VVF's without tissue interposition can be equally successful as primary repairs without tissue interposition⁶⁶. In 2014, Miklos and Moore reported a 100% cure in a 11 patients who previously failed VVF repair using a laparoscopic

extravesical technique without an omental flap. These 11 women had a total of 17 previous VVF repair surgeries, three of which included interposed omental flaps¹².

An interposition graft for VVFs works on 2 theoretical premises: 1) it functions as a barrier and 2) it introduces vascularity and theoretically lymphatics to improve tissue growth and maturation. It has been the authors' experience when operating on patients with failed VVFs with omental flaps, upon dissection of the vesicovaginal junction there was not only a lack of increased vascularity in the area but there was no evidence whatsoever of an interposition graft. This finding brings into question just how viable are the two theoretical benefits of an omental flap? Omental interposition grafts have never been *proven* to yield a higher cure rate for VVF repairs. Perhaps the most important part of the surgery is the actual repair fistula ie the bladder and the vagina and not the addition of the interposed omentum.

Although some might suggest there is little or no morbidity using an omental graft in experienced hands, the authors believe any added surgical procedure is not without risks. Based on the authors' experience reentry into abdomens with VVF repairs with an omental interposition have extensive adhesions which theoretically increases the chance of extending surgical time, blood loss and intraoperative morbidity as well as the potential for pelvic pain associated with adhesive disease.

In theory a high success rate can be attributed to meticulous dissection as well as a multi-layer closure which includes a double-layered bladder closure as supported by Sokol et al.⁶⁷ as well as aggressive testing of the bladder's suture line. In a study using 24 mongrel dogs, Sokol et al suggests that a double-layer closure of cystotomy is superior to a single-layer closure and may prevent fistula. Though a cursory review of the data suggests a trend revealing the more sutures that are used for fistula closure the greater the success rate of the VVF repair, this data is not statistically significant.

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The only way to determine "good tissue approximation" in VVF repair is to objectively determine a "water tight seal". A visual inspection of tissue approximation alone, without retrograde filling the bladder and stressing the suture line, is probably not the best measure of suture line integrity. However, standardization of the technique to determine a "watertight seal" has never been defined and this is apparent in the lack of consistency found in the VVF literature. A review of this table suggests 45.08% of the publications did not even perform a bladder test on patients with a VVF repair. The other 54.92% of patients had bladder testing with bladder capacities ranging from 75mL -400mL. Most bladder fills used normal saline and 26.23% of the studies reveal the use of saline and dye. Failure to report bladder testing does not necessarily mean it was not done but based on each published paper we must assume it was not done. The authors of this paper believe bladder testing is such an important step to VVF repair that it should be recorded and listed as part of each author's technique. Failure to perform an intraoperative bladder test after a VVF repair is at best careless as it has little if any morbidity and takes little time to perform. If the surgeon identifies a persistent leak despite the initial repair, he/she can reinforce the repair immediately and improve the chance for a successful VVF repair. Perhaps there is not an absolute volume to instill for a perfect bladder test but it would certainly make sense to truly test the integrity of the sutures line. Example: Before attempting a bungee jump you would not test the bungee cord with only 30 Kg. sack of sand when some potential jumpers might weigh 150 Kg. Why would it be any different when testing a bladder repair? The authors recommend using, what is considered a normal bladder capacity, at least 300 cc. at the time of bladder fill to test the suture line integrity. They also recommend using some type of contrast i.e. povidone or methylene blue, making small leaks easier to see.

Defining and comparing these two laparoscopic techniques of laparoscopic VVF repair with and without omental flaps is long overdue as there has been a lack of clarity in the literature. From pooling data, the surgical technique (transvesical vs. extravesical), bladder layer closure, vaginal layer closure, interposition, and bladder testing dye showed no statistical differences. However, laparoscopic VVF repair with bladder fill test had statistically significant higher success rate compared to those without bladder fill test.

The limitations of this systematic review include differences in follow-up period and no randomized controlled trials. Most of the studies included in this review are case series and case reports. Therefore, meta-analysis could not be performed. As a result, conclusion on the best surgical technique of laparoscopic VVF repair cannot be drawn. Further RCTs should be conducted.

The decision to approach, technique, interposition grafts, and layers of closure remains controversial and remains a personal decision based upon a surgeon's experience and comfort level. Vasavada and Raz (editorial comment)⁶⁸ said it most eloquently: "The best chance for ultimate success of vesicovaginal fistula repair is achieved not only with the first repair, but also the approach most familiar to the surgeon". No matter the approach the authors believe the most important aspect of the VVF repair remains adequate dissection, a watertight seal and good postoperative bladder decompression to allow for tissue healing.

Conflicts of interest: None

Table5- PRISMA checklist

Section/topic	#	Checklist item	Reported on page #
TITLE	_		
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT	<u> </u>		
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2-3
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	5-7
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	6-7
METHODS	<u> </u>		-
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	7
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	7
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	8
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	8
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	9
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	9
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	9
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	9

Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	9
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I ²) for each meta-analysis.	9
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	9
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	9
RESULTS	-		
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	10
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	10-18
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	9
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	13-18
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	N/A
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	9
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	19-20
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	20-25
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	25
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	25
FUNDING	<u> </u>		
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	25

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