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REVIEW

Efficacy and safety of uterine manipulators in laparoscopic surgery: a review

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Abstract
Purpose This review aims to objectively assess the efficacy and safety of uterine manipulators as reported in scientific literature. Furthermore, it evaluates as to which manipulator best suits which surgical procedure.
Methods PubMed, Embase, Web of Science, COCHRANE, CINAHL, Academic Search Premier, Science Direct and the MAUDE database were searched. Technical information was retrieved from the manufacturers.
Results 25 articles covering 10 uterine manipulators were found. Studies regarding implementation and use of manipulators are scarce; only two surveys were found comparing different manipulators. Moreover, clinical evidence proving the efficacy of manipulators with respect to prevention of complications, inherent to laparoscopic surgery, does not exist.
Conclusion The use of uterine manipulators is well established and it is clear that uterine manipulators offer the easiest way to handle the uterus during surgery. However, detailed information regarding efficacy and safety is scarce. Clinical evidence substantiating the assumed mechanism of prevention of ureter injuries was not found. Our review did not find the optimal manipulator. Some are more versatile than others and not all instruments are appropriate for all types of surgery. Therefore, gynecologists should choose the manipulator that best suits the type of surgery that is performed.

Keywords Hysterectomy · Laparoscopy · Review · Uterine manipulator

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Introduction

Uterine manipulators are widely adapted surgical instruments that facilitate various surgical procedures. In gynecology, the importance of a uterine manipulator regarding the prevention of ureter injuries during laparoscopic hysterectomy (LH), has been highlighted [1]. This reduced risk with respect to ureter injury is reported in several studies [1–6]. According to these publications, this may be achieved in several ways. Firstly, by lateralising the uterus, manipulators facilitate a perpendicular dissection of the uterine artery. Secondly, they elevate the uterus exposing the cul-de-sac, especially important in case of endometriosis. Thirdly, uterine manipulators provide delineation of the vaginal fornices, necessary for colpotomy and maintain the pneumoperitoneum after the vagina is incised. Finally manipulators increase the distance between the cervix and ureter by pushing the uterus cephalad, thus allowing safer dissection around the cervix. Meanwhile, it remains questionable if these advantages have been well researched. Although several surveys are available that offer an overview of different manipulators and their capabilities, they do not address the efficacy and patient safety of the different manipulators [7, 8]. Since the

indications for laparoscopy in gynecology are expanding, manipulators are likely to be found more often in the operation room and in different procedures. Without an objective overview, making an informed decision when introducing a uterine manipulator in daily surgical practice will be difficult. To obtain the necessary information, a literature review was performed to gather all published data regarding existing manipulators and their mode of action. These data were combined with an overview of reported adverse effects during the use of a uterine manipulator. With this review, we aim to objectively assess the efficacy of uterine manipulators as reported in scientific literature and to evaluate as to which manipulators best suit which surgical procedure.

Materials and methods

A review of literature was performed, searching PubMed, Embase, Web of Science, COCHRANE, CINAHL, Academic Search Premier and Science Direct. Our search strategy was finalised by the research librarian of the medical library at the Leiden University Medical Centre (LUMC). The following terms were used: hysterectomy (MeSH), colpohysterectomy, (gyn(a)ecologic) surgical procedures (MeSH), uterus (MeSH), uteri, colon (MeSH), colectomy (MeSH), sigmoid (MeSH), sigmoidectomy, uterine diseases (MeSH), mobilizer, mobiliser, manipulator. This review focusses on all manipulators suitable for (total) laparoscopic hysterectomy ((T)LH), since these instruments are most versatile. Manipulators frequently used in clinical practice were added to the search strategy. Reports on the manipulators were also searched with "Google". We crosschecked the reference lists of retrieved articles for relevant studies. Articles were selected by LH and CA, with FWJ acting as third reviewer in case of disagreement. All full text articles, with uterine manipulators and their actions as main subject, were included. Articles not focussing on the actions of a manipulator were excluded. Articles describing manipulators and the possible spread of malignant cells were also excluded. Although this is a very important topic, it reaches beyond the bounds of what we intended to evaluate. When only an abstract was available we contacted the author for a complete copy of the article. We contacted the manufacturer for further details in case the company's website provided insufficient information. Qualifications on manipulators as used by original authors were adapted in this review.

Finally, the manufacturer and user facility device experience (MAUDE) database was checked for all reported complications over the last 10 years. This database is a passive surveillance system of the FDA for medical device safety. This study was exempt from approval by the Medical Ethics Committee.

Results

299 references and 1 article from an online journal were found, of which 263 references were excluded based on title or content of the abstract and 6 due to missing full text versions (Fig. 1). Of the remaining 32 references LH and CA disagreed on the inclusion of 9 titles. Of these 9, 7 titles were excluded after assessment by FWJ. These articles did not sufficiently focus on uterine manipulators or its actions. Finally, a total of 26 references and the article from the online journal covering 10 manipulators suitable for (T)LH were evaluated in our review (Table 1) [1–26]. The Hourcabie, a frequently mentioned manipulator, could not be assessed since no information regarding its manufacturer was found. The Koninckx manipulator, Donnez manipulator, McCarus Volker Fornisee System and Secufix Uterus Manipulator were also not described in this review since no scientific publications were available on these instruments.

For purpose of accessibility, the literature is presented according to the manipulator. Table 2 offers an overview of the manipulators and their characteristics. It is largely based on the only two existing surveys that evaluated and compared different uterine manipulators [7, 8]. Table 3 states all reports in the MAUDE database.

The Hohl manipulator is a reusable instrument. It has a 130° range of motion in the anterior-posterior plane. Lateral movement and elevation are given to be good and handling is reported to be easy. However, assembly is stated as difficult [7]. Most publications were found regarding this manipulator: three prospective studies, one retrospective study, a product survey and one case report [4, 7, 12–16]. One retrospective study and one prospective cohort study were performed by Mueller et al. [4, 14], including 44 and 567 patients, respectively. One ureter injury, four bladder injuries and one vagina injury occurred. In an additional prospective study, the Hohl manipulator was compared in women with BMI <30 (219 patients) versus BMI >30 (38 patients) [13]. 1 ureter injury, 1 bladder and 1 vaginal injury were observed, all in the group with BMI <30. However, there was a significant difference in uterine weight with smaller uteri in the group with BMI >30 (246 vs. 185 g). Another prospective cohort was published of 1432 patients undergoing total intrafascial laparoscopic hysterectomy (TAIL) using a Hohl manipulator, experiencing 1 ureter and 8 bladder injuries [15]. Finally, a case report exists describing a uterine perforation and bowel perforation in a patient were a Hohl manipulator

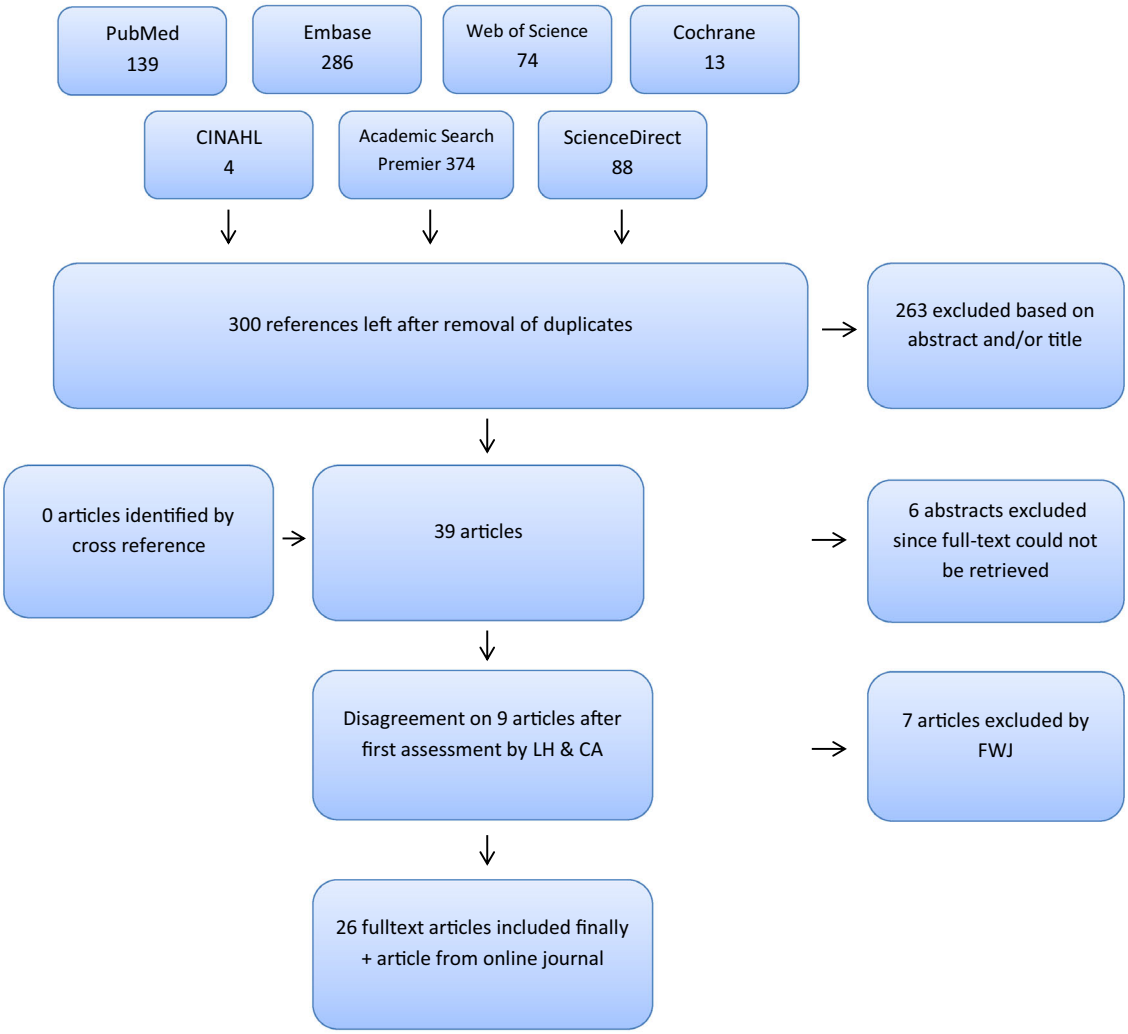

Fig. 1 Flow diagram of study selection

was used [12]. No reports on this manipulator were found in the MAUDE database.

The Clermont Ferrand manipulator is a reusable instrument and offers 140° range of motion in the anterior-posterior plane. Lateral motion and elevation are mentioned to be good and handling is easy [7]. There are no studies that evaluate the efficacy of this instrument and no reports in the MAUDE database exist.

The Clearview manipulator is a lightweight disposable instrument. With 210°, it has the greatest range of motion in the anterior-posterior plane of all the manipulators. It was previously known as the Endopath uterine manipulator. It is reported to have excellent characteristics [7]. Unfortunately it does not offer delineation of the vaginal fornices and it cannot maintain the pneumoperitoneum, making it less suitable for total laparoscopic hysterectomy (TLH). It allows the manipulation of the uterus by the gynecologic surgeon, without the need of an assistant holding the manipulator. This manipulator is the only instrument to have been tested in a randomised trial [17]. In this trial, 50 patients were randomly assigned to a Clearview manipulator or a Cohen cannula. Various laparoscopic procedures were performed except for (T)LH. The authors found a better range of motion (120° vs. 84°, $p < 0.0001$, anterior; −20° vs. −8°, $p < 0.0001$, posterior) in favour of the Clearview manipulator. However, the Clearview took longer to insert (116 vs. 27 s, $p = 0.02$). No significant differences were found in other parameters, such as ease of use. Two minor complications occurred in the group of the Clearview manipulator: in both cases a cervical perforation occurred during dilation because of cervical stenosis. Two reports were found in the MAUDE database, concerning one case where the manipulator disintegrated inside the patient and one case where parts of the manipulator came loose and remained inside a patient.

Table 1 Review of Literature

Manipulator	References	Type	Subject	No. of patients	Complications/injuries
Hohl	Mueller et al. [4]	Retrospective cohort	TLH with Hohl	44	None
	Mueller et al. [13]	Prospective Controlled	BMI <30 vs. BMI >30	219 vs. 38	1 ureter, 1 bladder, 1 vagina[a]
	Mueller et al. [14]	Prospective cohort	TLH with Hohl	567	1 ureter, 4 bladder, 1 vagina
	Hohl et al. [15]	Prospective cohort	TAIL vs. AH vs. VH	1432 TAIL	1 ureter, 8 bladder
	Janssen et al. [16]	Retrospective case analysis	Ureter injuries		
	Akdemir and Cirpan [12]	Case report	Complication Hohl	1	Uterine rupture and bowel penetration
	Mettler and Nikam [7]	Product review	Survey manipulators		
Clermont Ferrand	Janssen et al. [16]	Retrospective case analysis	Ureter injuries		
	Mettler and Nikam [7]	Product review	Survey manipulators		
Clearview	Sharp et al. [17]	Randomised trial	Clearview vs. Cohen cannula	25 vs. 25	2× perforated uterus during dilation of the cervix
	Mettler and Nikam [7]	Product review	Survey manipulators		
RUMI I + KOH	Keriakos and Zaklama [2]	Prospective cohort	TLH with RUMI + KOH	25	None
	Ng et al. [5]	Retrospective cohort	TLH with RUMI + KOH	435	Ureter 0.2 %, Bladder 0.2 %
	Ng and Chern [6]	Retrospective cohort	TLH with RUMI + KOH	512	Ureter 0.2 %, Bladder 0.4 %, Vagina 1 %
	Koh [3]	Product review	TLH with RUMI + KOH		
	Wu et al. [18]	Case Report	Complication RUMI	2	Uterine rupture
	Ellett et al [26]	Case Report	Complication RUMI	1	KOH cup left behind
	Mettler and Nikam [7]	Product review	Survey manipulators		
Vcare	Greenberg [19]	Product Review	Vcare		
	Mettler and Nikam [7]	Product review	Survey manipulators		
	Janssen at al. [1]	Retrospective case analysis	Ureter injuries		
Mangeshikar	Mettler and Nikam [7]	Product review	Survey manipulators		
Vectec	Tamburro [20]	Prospective cohort	Effect suction on endometrium	10	
McCartney Tube	McCartney et al. [21]	Retrospective cohort	TLH + McCartney	1500	
	McCartney and Johnson [22]	Retrospective cohort	TLH + McCartney	73	
	Janssen et al. [16]	Retrospective case analysis	Ureter injuries		
	Elkington and Chou [23]	Review	TLH		
Valtchev	Reich and Maher [24]	Product review	Surgical instruments for laparoscopy		
	Bernstein [25]	Product review	Valtchev		

TAIL, total intrafascial laparoscopic hysterectomy; AH, abdominal hysterectomy; VH, vaginal hysterectomy; TLH, total laparoscopic hysterectomy

[a] All injuries occurring in pts with BMI <30

Table 2 Uterine manipulators [7, 8, 13, 14, 17, 19–25]

		Range of motion			Characteristics					Use			
		ant-post	lat[a]	Elevation	Type	Traumatic	Reusable	Delineation	Pneumoperitoneum	handling	assembly	Suitable	Less Suitable
Hohl		130	+++	++	screw	Yes	Yes	++	++	+++	+	(T)LH	Endometrioses of the cul-de-sac
Clermont Ferrand		140	+++	+++	screw	Yes	Yes	+++	+++	+++	+	(T)LH, endometriosis of cul-de-sac	Cervical preservation, due to dilation to Hegar nr. 9
Clearview		210	+++	++	balloon	Yes	No	-	-	+++	+++	All procedures except (T)LH, including chromopertubation	(T)LH
RUMI System[b]		140	+++	+	Balloon	Yes	Partly	+++	+++	++	+	Alround, (T)LH	Endometrioses in the cul-de-sac, narrow vagina
RUMI II system[b]		140	+++	?	balloon	Yes	Partly	yes	yes	++	++	Insufficient information	
Vcare		*na*	++	++	balloon	?	No	+++	+++	+++	+++	(T)LH, alround	Large / heavy uteri
Dr Mangeshikar[c]		?	+++	+++	Tenaculum	Yes	Yes	+++	+++	+++	+++	(T)LH, endometriosis of cul-de-sac	
Vectec		*na*	?	?	Suction / screw	No	No	Yes	yes	?	?	Insufficient information	
McCartney tube		-	-	-	-	No	No	+++	++	+++	*na*	(T)LH	Other gynaecological procedures
Valtchev		135	?	?	tenaculum	Yes	Yes	yes	yes	+++	+++	around	

Table based on available data in publications and from manufacturers

+++, good; ++, moderate; +, poor; −, does not support; na, not applicable; ?, not found; (T)LH, (total) laparoscopic hysterectomy

[a] Not independent movement, except for Mangeshikar manipulator

[b] RUMI system consists of the RUMI manipulator, the Koh cervical cup, and the Koh colpo-pneumo-occluder

[c] Also offers independent levorotation and dextrorotation

The RUMI system consists of the RUMI manipulator, the Koh cervical cup and the Koh colpo-pneumo-occluder. It has a 140° range in the anterior-posterior plane. Along with the Hohl manipulator, most publications were found on this instrument: two retrospective and one prospective studies, two case reports and several product reviews [2, 3, 5–7, 18, 26]. However, the 2 retrospective cohort studies, including 435 and 512 patients, describe the same patient population, with one containing more patients due to a longer inclusion period [5, 6]. Injury rate in the largest cohort was 0.2 % for ureter, 0.4 % for bladder and 1 % for the vagina. The prospective study describes a cohort of 25 patients [2]. Two case reports exist: the first is a uterine rupture in 2 patients due to hyperinflation of the intra-uterine balloon of the RUMI manipulator, and the second a KOH cup that remained inside a patient and was discovered 14 months after surgery [18, 26]. Lastly, several reports were found in the MAUDE database on the disintegration of the instrument or on parts being left behind, in some cases leading to lacerations of the vaginal wall. The RUMI system has been updated; however, no studies were found on the RUMI II system.

The Vcare manipulator is a lightweight disposable instrument. It does not offer independent motion of the intra-uterine tip, rather it uses leverage to manipulate the uterus. The Vcare has a wide range of motion, it is said to offer good delineation and to maintain the pneumoperitoneum well. In addition, handling is easy. However, the lightweight design is reported to be less suitable to manipulate larger uteri [7, 8, 19]. Multiple reports were found in the MAUDE database on disintegration of the instrument or on parts being left behind. Furthermore, lacerations of the vaginal wall have been described. Lastly, the melting of the cervical cup was mentioned in one report, however, without causing harm or damage to the patient.

The Dr. Mangeshikar manipulator is the only instrument to offer independent levorotation and dextrorotation of the intra-uterine tip. It offers a wide range of motion in all directions and assembly and handling are mentioned to be easy [7]. Unfortunately, no additional publications are available on this instrument.

The Vectec manipulator, like the Vcare, uses leverage to manipulate the uterus instead of an intra-uterine tip with independent movement. It is a disposable instrument. One

Table 3 Complications caused by uterine manipulators based on MAUDE database and literature

Manipulator	Event	Measures needed?
Hohl	Uterine rupture and bowel penetration	Laparotomy for bowel repair
Clearview	Parts of the manipulator left behind in patient	
	Disintegration of manipulator while inside patient	Removal with hysteroscopy
	Uterine perforation due to cervical dilation	
RUMI I	Laceration of vaginal wall (multiple reports)	Suturing
	Excess haemorrhage from laceration	Blood transfusion
	Parts of the manipulator left behind in patient (multiple reports)	
	Disintegration when removing the manipulator	
	Spontaneous release of cup during colpotomy	Prolonged operation time to check integrity of ureters
	Retroperitoneal haematoma caused by uterine perforation after hyperinflation of the intra-uterine balloon	Laparotomy and uterine artery ligation
	Vaginal mucosa stuck in RUMI	
Vcare	Disintegration when removing the manipulator	
	Parts of the manipulator left behind (multiple reports)	
	Laceration of vaginal wall (multiple reports)	Suturing
	Perforation of vagina and cervix due to cup	
	Perforation of uterus with intra-uterine tip	
	Repetitive strain injury of the assistant	
	Melting of the cup	

study was found, demonstrating that the suction mechanism by which the manipulator secures itself, does not modify the endometrium and therefore should be safe to use [20]. The Vectec is also available with a screw mechanism.

The Valtchev manipulator is one of the oldest instruments in our study. It is a reusable instrument and offers 135° movement in the anterior-posterior plane. It is reported to be easy to assemble and handle [7, 25]. The McCartney tube was also included in this review. Strictly speaking, it is not an intra-uterine manipulator as it does not have an intra-uterine section, therefore not allowing movement of the uterus in a frontal or horizontal plane. It does, however, offer delineation of the vaginal fornices and is able to maintain the pneumoperitoneum well. It also allows the introduction of materials through the vaginal tube instead of the transabdominal trocars. Since it provides excellent cephalad movement of the uterus, it has a place among the uterine manipulators as will be discussed later. Two retrospective cohorts (73 and 1500 patients) describe the McCartney tube as manipulator [21, 22]. Regrettably, no reports on ureter injuries are made in these cohorts. No reports were found in the MAUDE database.

Discussion

This review offers an overview of all scientific literature on manipulators. There is a paucity of well-designed studies that assess the different instruments. Only one randomised trial exists and it addressed the Clearview manipulator [17]. Based on our review, the Clermont Ferrand, Dr. Mangeshikar, Valtchev and RUMI System manipulators seem to be most versatile due to excellent capabilities, although the Clermont Ferrand and RUMI System are considered difficult to assemble. The Vcare, Clearview and Valtchev are very user friendly. However, the Vcare is considered too light to use in larger uteri. The Clearview manipulator lacks a cervical cup and cannot maintain the pneumoperitoneum, making it less suitable for TLH; however, it may be a useful instrument for other gynecological procedures. The Dr. Mangeshikar manipulator is the only instrument in our review to provide independent levorotation and dextrorotation of the uterus, thereby presenting the uterine arteries without having to stretch the manipulator too far laterally. In theory, this may offer an advantage especially in case of vaginal atrophy or stenosis. The Clermont Ferrand and the Dr. Mangeshikar offer the best exposure of the cul-de-sac due to excellent uterine elevation. In case of endometriosis of the cul-de-sac, these two instruments may be the instruments of choice.

Surprisingly, little evidence exists regarding the efficacy and safety of uterine manipulators. Furthermore, although many authors feel that the cephalad motion of the uterus is extremely important for avoiding urinary tract injuries, since this increases the distance between ureter and cervix [3–5], no study exists demonstrating the actual mechanism of the increased distance between cervix and ureter by

pushing the uterus cephalad. Only one study mentioned having visualised an increased distance between ureter and cervix when using the RUMI system by placing lighted ureteral stents [3]. However, the author did not explain how this was performed nor did he supply figures of his observations. The same author also states that distance between ureter and cervix actually decreased when using a cervical cup that is too large. If indeed true, this finding is worrisome, since it implies a reduction of patient safety when using an improper cervical cup. Moreover, no studies are available on this specific subject, making it impossible to predict the correct shape of the cervical cup, including cups of existing manipulators. In addition, several articles were found where this movement is provided by alternative methods [9–11].

Considering the low incidence of ureter injuries, it will be difficult to demonstrate the effect of a uterine manipulator as ultimate tool for the prevention of these injuries. Moreover, ureter injury rate depends on far more than just the use of a uterine manipulator, such as learning curve and experience of the gynecologist, and the presence of additional disease, e.g. endometriosis. Subsequently, although the earlier mentioned Delphi study by Janssen et al. [1] is the best evidence we have regarding the prevention of ureter injuries, it is important to realize that the recommendations on ureter injuries were established based on expert opinions rather than clinical evidence. This is substantiated by the analyses of 31 ureter injuries performed by the same author [16]. A uterine manipulator was used in the vast majority (83.9 %) of cases of ureter injury. These results affirm that a uterine manipulator is not the ultimate tool to prevent ureter injuries.

Unfortunately, statements regarding the safety of the reviewed manipulators cannot be made. Since there certainly is under-reporting of complications, accurately determining a rate of complications caused by a uterine manipulator is impossible. However, a trend is seen that (partly) disposable, relatively lightweight uterine manipulators that need assembly are at risk for adverse events due to disintegration of the instrument or to parts being left behind in patients.

A cost analysis of the manipulators could not be performed, due to variable prices between countries, sometimes even between hospitals. Given this variability and since we compare (partly) disposable manipulators to reusable ones, we feel a full cost analysis is unlikely to add significant data to our review.

Although our search did not include the possible effects of manipulators on uterine malignancies, this topic should be addressed since laparoscopy is increasingly implemented in gynecologic oncology. In both cervical and endometrial malignancies, clinico-pathological parameters such as infiltration depth and lymphovascular space invasion (LVSI) may be influenced when a manipulator is used [27–31]. However, it is hypothesised that other factors such as artefacts and tissue handling contributed to these findings. More importantly, no negative effects on the oncological outcome were found in these studies. In addition, larger studies including a prospective randomised trial did not find this influence on clinico-pathological parameters [31–36]. Based on these studies it can be concluded that the use of a uterine manipulator during gynecologic oncology procedures is unlikely to negatively affect a patients oncological outcome. However, in absence of definitive evidence, several authors suggest closing the fallopian tubes via cautery or clipping prior to the insertion of a manipulator to prevent spread of malignant cells into the abdomen.

The shortcoming of our study is the limited number of unbiased papers and randomised trials available on this subject. Since the aim of our study was an objective evaluation of the existing literature, we did not test the instruments ourselves. This makes an extensive evaluation of the manipulators more difficult. As a result, all characteristics of the manipulators are based mostly on the two available surveys. Furthermore, strong conclusions with respect to complications during the use of certain manipulators cannot be made due to earlier mentioned reasons.

However, to our knowledge, this review is the first review to independently assess manipulators based on available studies and on safety reports. In contrast with some studies we've found, our study is not commercially driven. Therefore, it offers valuable additional information to existing literature. Furthermore, our finding that statements with respect to the prevention of ureter injuries are not substantiated by clinical evidence has important implications. Given the possible adverse effects, our study demonstrates that a uterine manipulator should not be introduced without fair consideration. Ideally, for every procedure, the most appropriate manipulator should be considered.

Conclusion

Uterine manipulators are very useful instruments that help expose the anatomy during surgical procedures. However, evidence regarding their efficacy and safety is scarce. Although uterine manipulators are probably the easiest way to handle the uterus during laparoscopy, alternatives without manipulators have been published. More importantly, evidence proving how manipulators prevent ureter injuries is absent. The findings of 1 study, mentioning a decrease in distance between cervix and ureter when using too large cervical cups, are worrisome and in need of further investigation [3]. Subsequently it is unclear if

uterine manipulators are the ultimate tool to prevent ureter injuries.

Conclusions with respect to reported complications caused by uterine manipulators cannot be made, due to underreporting. However, it appears that lightweight disposable manipulators in need of assembly seem to be at risk to cause specific adverse effects. Therefore, they should be used with extra care.

Our literature review did not provide the ultimate uterine manipulator. The Clermont Ferrand and Dr. Mangeshikar manipulator seem to be the most versatile, and the latter is the only manipulator in our review to offer independent levorotation and dextrorotation. However, no publications such as cohort studies or randomised trials exist on these instruments. In all, gynecologists should choose the uterine manipulator that best meets the requirements for the type of surgery to be performed.

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Conflict of interest van den Haak L., Alleblas C., Nieboer T. E., Rhemrev J. P. and Jansen F. W. have no conflicts of interest or financial ties to disclose.

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