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Randomized Controlled Trials for Comparison of Laparoscopic Versus Conventional Open Catheter Placement in Peritoneal Dialysis Patients: A Meta-Analysis

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Abstract

Aim The application of laparoscopic catheterization technology in peritoneal dialysis (PD) patients has recently increased. However, the advantages and disadvantages of laparoscopic versus conventional open catheterization are still controversial. The aim of this meta-analysis is to assess complications of catheterization in PD patients and to provide a reference for the clinical choice of PD catheter placement technique. Methods We searched numerous databases, including Embase, PubMed, CNKI and the Cochrane Library, for published randomized controlled trials (RCTs). Results Eight relevant studies (n=646) were included in the meta-analysis. The pooled results showed a lower incidence of catheter migration (P: 0.03, OR: 0.42, 95% CI: 0.19 to 0.90) and malfunction (P: 0.008, OR: 0.41, 95% CI: 0.21 to 0.79) but a higher incidence of bleeding (P: 0.02, OR: 3.25, 95% CI: 1.18 to 8.97) with a laparoscopic approach than with a conventional approach. There was no significant difference in the incidence of obstruction (P: 0.24, OR: 0.32, 95% CI: 0.05 to 2.10), hernia (P: 0.20, OR: 0.38, 95% CI: 0.09 to 1.68), leakage (P: 0.23, OR: 0.69, 95% CI: 0.38 to 1.26), mechanical dysfunction (P: 0.90, OR: 0.96, 95% CI: 0.48 to 1.91), malfunction (P: 0.008, OR: 0.41, 95% CI: 0.21 to 0.79), perforation (P: 0.97, OR: 0.95, 95% CI: 0.06 to 15.42), peritonitis (P: 0.13, OR: 0.95, 95% CI: 0.42 to 1.12) or tunnel or exit-site infections (P: 0.49, OR: 0.95, 95% CI: 0.71 to 2.02). Conclusion Laparoscopic catheterization and conventional open catheter placement in PD patients have unique advantages, but laparoscopic catheterization may be superior to conventional open catheter placement. However, this conclusion needs to be confirmed with further large-sample-size, multi-centre, high-quality RCTs.

Introduction

Alternative treatments for end-stage renal disease (ESRD) include kidney transplantation, haemodialysis and peritoneal dialysis (PD). PD has become the preferred alternative treatment for end-stage renal disease because of its low cost, simple technology, strong patient independence, few dietary restrictions, stable haemodynamics and good protection of residual renal function[1]. Although peritoneal dialysis is an effective treatment for end-stage renal disease, the success of peritoneal dialysis depends on successful catheterization. Successful placement of PD catheters can improve the efficiency of peritoneal dialysis, reduce complications such as peritonitis and drifting catheters, and prolong the life of patients. Successful placement is also a prerequisite for the effective progress of PD[2]. The main operation methods of peritoneal dialysis catheterization are traditional operation and laparoscopic operation. The traditional operation is currently the most commonly used method of peritoneal dialysis catheterization. The risk of injury and bleeding is relatively small, the operation is simple, and the cost is low, but the failure rate is high[3]. By virtue of the advantages of visualization during laparoscopic operation, the drift rate[4] and blockage rate[5] of the PD tube can be effectively reduced. At the same time, compared with the traditional operation, laparoscopic operation has the advantages of less trauma and faster recovery after the operation[6], but it requires expensive equipment and specially trained personnel; thus, the procedure is not easily popularized.

A previous meta-analysis compared the complications between laparoscopic placement and conventional insertion of a catheter[7]. Nonetheless, as several new RCTs have been published recently, an updated meta-analysis is needed to re-evaluate the results.

In this meta-analysis, we systematically reviewed and analysed previous randomized controlled trials to compare the complications from conventional versus laparoscopic catheter placement in peritoneal dialysis patients. The results of our study will provide a reference for future methods of peritoneal dialysis catheterization.

Search Strategy

Three researchers (Zhang Y, Zhang P and Sun ML) performed a comprehensive literature search, and 8 relevant studies were obtained that conformed to all of the eligible criteria. We searched the electronic databases PubMed, Embase, CNKI, and Cochrane Library for studies published prior to May 6, 2019. The following keywords were used: “Laparoscopic”, “Peritoneal Dialysis”, “Dialysis”, “Conventional”, “Open”, and “Catheter”. Reference lists from the identified studies were included to enrich the analysis.

Selection Criteria

Three researchers (Zhang Y, Zhang P and Sun ML) conducted a preliminary review independently to search for randomized controlled trials (RCTs) that met the inclusion criteria. Any discrepancy was resolved by consensus and discussion **(Fig 1)**. The following criteria were used for inclusion: 1) the study was an RCT; 2) studies compared the

outcomes of a laparoscopic PD catheter insertion technique with those of conventional insertion; 3) relative risk (RR) and 95% confidence interval (CI) were calculated; and 4) more than 1 complication was described. The main characteristics of the included studies are listed in **Table 1**.

Table 1. Main characteristics of the included studies.

Study	Country	Design	Sample Size (n)		Age (year)		Follow-up (month)		Outcomes
			Laparoscopic	Conventional	Laparoscopic	Conventional	Early	Late	
Gadallah 1999[8]	USA	RCT	76	72	45.0±1.8	47.2±2.4	0.5	0.5-8	complications
Wright[9] 1999	UK	RCT	24	21	46.4±14.8	49.3±20.2	1.5	1.5-26	complications
Tsimoyiannis 2000[10]	Greece	RCT	25	25	53.7±12.2	61.4±6.1	36		complications
Jwo 2010[11]	Taiwan	RCT	37	40	56.6±13.4	54.4±16.5	1	1-8	complications
Laanen 2018[12]	Netherlands	RCT	46	44	62.6±14.1	64.5±14.1	8		complications
Qiao 2012[13]	China	RCT	58	58	47.64±13.73		24		complications
Qu 2017[14]	China	RCT	35	35	39.4±11.3	39.8±11.2	12		complications
Xu 2010[15]	China	RCT	25	25	53.6±14.6	59.2±16.8	18		complications

Risk Of Bias Assessment

The quality of all trials was assessed by three authors (Zhang Y, Zhang P, and Sun ML) independently according to the Cochrane quality criteria **(Table 2)**. Any disagreement was settled by discussion with a fourth author (Wang B) until a consensus was reached.

Statistical Analysis

Revman 5.3 software was used to perform the statistical analyses. The odds ratio (OR) with its 95% confidence interval (CI) was used for dichotomous data. If there was no significant heterogeneity, a weighted fixed-effect model was used. Otherwise, a random-effects model was used[16]. Heterogeneity was analysed statistically by the I^2 and Chi^2 statistics. The critical value for homogeneity was a P value less than 0.05. A sensitivity analysis was conducted by omitting each study in turn to evaluate the quality and consistency of the results.

Heterogeneity was determined as follows: an I^2 statistic of 0% to 25% was considered light heterogeneity; 25% to 50% was medium heterogeneity; 50% to 75% was heavy heterogeneity; and 75% to 100% was powerful heterogeneity. The P value was determined using the $\chi 2$ test; it was considered statistically significant when $P < 0.05$[17].

Table 2. Risk of bias in published randomized control trials.

Study	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other bias	Score
Gadallah 1999	UC	UC	Low risk	Low risk	Low risk (Loss to follow-up: 0)	Low risk	Low risk	5
Wright 1999	Low risk	Low risk	Low risk	Low risk	Low risk (Loss to follow-up: 0)	Low risk	Low risk	5
Tsimoyiannis 2000	Low risk	Low risk	Low risk	Low risk	Low risk (Loss to follow-up: 3/50)	Low risk	Low risk	7
Jwo 2010	UC	UC	Low risk	Low risk	Low risk (Loss to follow-up: 0)	Low risk	Low risk	5
Laanen 2018	Low risk	Low risk	Low risk	Low risk	Low risk (Loss to follow-up: 5/95)	Low risk	Low risk	7
Qiao 2012	UC	UC	Low risk	Low risk	Low risk (Loss to follow-up: 6/116)	Low risk	Low risk	5
Qu 2017	UC	UC	Low risk	Low risk	Low risk (Loss to follow-up: 0)	Low risk	Low risk	5
Xu 2010	UC	UC	Low risk	Low risk	Low risk (Loss to follow-up: 0)	Low risk	Low risk	5

UC: unclear

Results

Study Selection

We identified a total of 776 articles in the initial retrieval. In this study, 69 duplicate articles were discarded after carefully reviewing the titles and abstracts. When evaluated in detail, 697 articles were excluded because 189 were basic research studies, 171 were non-controlled studies, and 337 were case reports or reviews. The remaining 10 articles were reviewed for a more detailed assessment. An additional 2 articles were excluded for lack of available data. Finally, 8 studies with 646 participants fulfilled the inclusion criteria for this meta-analysis**.** The main characteristics of the RCTs (country, sample size, design, patient age, intervention and follow-up) included are described in **Table 1.** The retrieval strategy is described in the flow diagram **(Fig 1).**

Sensitivity analysis and publication bias

No significant heterogeneity was found in the results. Sensitivity analysis was performed to evaluate the stability of our results. The results showed that no individual studies significantly affected the heterogeneity.

Catheter-related complications

Migration: 5 studies[10, 11, 13-15] assessed catheter migration in a total of 440 patients/ person-time, 217 of whom were assigned to laparoscopic groups and 223 to conventional open groups. Because there was no significant heterogeneity, the fixed-effects model was used (I^2 = 34%). The statistical analysis showed a lower incidence of catheter migration in the laparoscopic group than in the conventional open group (P: 0.03, OR: 0.42, 95% CI: 0.19 to 0.90), as listed in **Table 3** and **Fig 2**.

Obstruction: Only 2 studies[13, 15] reported an incidence of obstruction involving 166 patients/ person-time, 83 of whom were assigned to laparoscopic groups and 83 to conventional open groups. Because there was no significant heterogeneity, the fixed-effects model was used (I^2 = 0%). The statistical analysis showed no significant difference between the 2 groups (P: 0.24, OR: 0.32, 95% CI: 0.05 to 2.10), as listed in **Table 3** and **Fig 2**.

Hernia: 3 studies[11, 13, 14] assessed the incidence of incisional hernias in a total of 243 patients/ person-time, 120 of whom were assigned to laparoscopic groups and 123 to conventional open groups. Because there was no significant heterogeneity, the fixed-effects model was used (I^2 = 0%). The statistical analysis showed no significant difference between the 2 groups (P: 0.20, OR: 0.38, 95% CI: 0.09 to 1.68), as listed in **Table 3** and **Fig 2**.

Leakage: The incidence of leakage was reported in 6 studies [8-11, 13, 14] involving 731 patients/ person-time, 368 of whom were assigned to laparoscopic groups and 363 to conventional open groups. Because there was no significant heterogeneity, the fixed-effects model was used (I^2 = 45%). The statistical analysis showed no significant difference between the 2 groups (P: 0.23, OR: 0.69, 95% CI: 0.38 to 1.26), as listed in **Table 3** and **Fig 2**.

Bleeding: The incidence of bleeding was reported in 4 studies[11-14] involving 353 patients/ person-time, 176 of whom were assigned to laparoscopic groups and 177 to conventional open groups. Because there was no significant heterogeneity, the fixed-effects model was used (I^2 = 0%). Compared with patients in the conventional open groups, patients in the laparoscopic groups showed a statistically significant increase in the incidence of bleeding ((P: 0.02, OR: 3.25, 95% CI: 1.18 to 8.97), as listed in **Table 3** and **Fig 2**. We believe the higher incidence of bleeding in the laparoscopic group may be due to the fact that the puncture procedure lacks sufficient monitoring of bleeding.

Mechanical dysfunction: 4 studies[8, 13-15] assessed the incidence of mechanical dysfunction in a total of 532 patients/ person-time, 270 of whom were assigned to laparoscopic groups and 262 to conventional open groups. Because there was no significant heterogeneity, the fixed-effects model was used (I^2 = 0%). The statistical analysis showed no significant difference between the 2 groups (P: 0.90, OR: 0.96, 95% CI: 0.48 to 1.91), as listed in **Table 3** and **Fig 2**.

Malfunction: Only 2 studies[8, 10]reported the incidence of obstruction involving 198 patients/ person-time, 101 of whom were assigned to laparoscopic groups and 97 to conventional open groups. Because there was no significant heterogeneity, the fixed-effects model was used (I^2 = 0%). The statistical analysis showed a lower incidence of malfunction in the laparoscopic group than in the conventional open group (P: 0.008, OR: 0.41, 95% CI: 0.21 to 0.79), as listed in **Table 3** and **Fig 2**.

Perforation: Only 1 study[8] reported the incidence of perforation, and it involved 148 patients/ person-time, 76 of whom were assigned to laparoscopic groups and 72 to conventional open groups. Because there was only 1 study describing perforation, heterogeneity analysis was not applicable. The statistical analysis showed no significant difference between the 2 groups (P: 0.97, OR: 0.95, 95% CI: 0.06 to 15.42), as listed in **Table 3** and **Fig 2**.

Infections

Peritonitis[8-11, 13-15], which was found in 749 patients/ person-time (P: 0.13, OR: 0.95, 95% CI: 0.42 to 1.12), and tunnel infections or exit-site infections[8, 9, 11], which were found in 315 patients/ person-time (P: 0.49, OR: 0.95, 95% CI: 0.71 to 2.02), resulting in removal of the catheter, were considered a failure with respect to catheter insertion. The fixed effects model was used because there was no significant heterogeneity in either peritonitis or tunnel exit-site infections resulting in removal of the catheter. The results showed no significant differences between the two groups, as listed in **Table 4** and **Fig 3**.

Table 3. The results of catheter-related complications in observational studies.

Infections		Results				Heterogeneity		
Parameter	N/P	Effects Model	Pooled Estimate	95% CI	P-value	Chi^2	I^2	P-value
Migration	7/440	Fixed	0.42	0.19 to 0.90	0.03	7.55	34%	0.18
Obstruction	2/166	Fixed	0.32	0.05 to 2.10	0.24	0.94	0%	0.33
Hernia	3/243	Fixed	0.38	0.09 to 1.68	0.20	0.29	0%	0.20
Leakage	8/731	Fixed	0.69	0.38 to 1.26	0.23	12.83	45%	0.08
Bleeding	3/263	Fixed	3.88	1.28 to 11.77	0.02	0.08	0%	0.96
Mechanical dysfunction	5/532	Fixed	0.96	0.48 to 1.91	0.90	2.54	0%	0.64
Malfunction	2/198	Fixed	0.41	0.21 to 0.79	0.008	0.06	0%	0.80
Perforation	1/148	Fixed	0.95	0.06 to 15.42	0.97	Not applicable		

N/P: No. of studies / No. of patients (person-time)

Infections		Results				Heterogeneity		
Parameter	N/P	Effects Model	Pooled Estimate	95% CI	P-value	Chi^2	I^2	P-value
Peritonitis	9/749	fixed	0.68	0.42 to 1.12	0.13	12.61	37%	0.13
Exit-site/tunnel infection	4/94	fixed	1.20	0.71 to 2.02	0.49	5.00	40%	0.17

Table 4. The results of infections in observational studies.
N/P: No. of studies / No. of patients (person-time).

Discussion

In 1959, Richard Ruben[18] successfully used peritoneal dialysis (PD) for the first time. Popovich and Moncrief developed continuous ambulatory PD, which promoted the use of PD[19]. Subsequently, the method of introducing catheters into the abdominal cavity was modified, and then open surgery, percutaneous puncture, peritoneoscopy and laparoscopic techniques were introduced[9, 20, 21]. Several authors favour laparoscopic catheterization rather than open catheterization and demonstrate the obvious advantages of laparoscopic catheterization in non-randomized trials[5, 22, 23]. However, due to the lack of RCTs with high quality and large sample sizes, this conclusion is still controversial.

Recently, a few RCTs examining the two techniques have been published. Gadallah et al. conducted an RCT with 148 patients addressing the use of the laparoscope for dialysis catheter implantation and provided us with some suggestions for catheter placement. Later, Jwo et al. conducted an RCT with 77 patients for comparison of conventional placement with laparoscopic-assisted placement of a Tenckhoff peritoneal dialysis catheter; they wrote a literature study and concluded that laparoscopic-assisted catheter placement exhibited no superiority to the conventional surgery technique. Our viewpoint was not consistent with his. To date, no meta-analysis of RCTs has been performed to compare the two methods. Therefore, we performed a meta-analysis to make it convenient for clinicians to select the appropriate surgical approach.

In this study, we conducted a meta-analysis to compare the complications of laparoscopic versus conventional catheter placement in peritoneal dialysis patients. Our results showed that laparoscopic insertion could significantly decrease the probability of migration, bleeding and malfunction. No significant difference was found in other complications, such as obstruction, hernia, leakage, mechanical dysfunction and perforation. No statistically significant difference was found in the incidence of peritonitis or exit-site/tunnel infection.

Compared with laparoscopic minimally invasive peritoneal dialysis catheterization, conventional peritoneal dialysis catheterization has the following disadvantages: 1) a long operation time, more bleeding, strong pain, a long incision length

and a slow recovery; 2) limited field of vision, not as open as laparoscopic minimally invasive surgery, blindness of catheter placement by hand leads to inaccurate catheter placement, easy to move or greater obstruction of the catheter by the greater omentum; 3) the incision infection rate is high, ESRD is often associated with a variety of diseases, poor resistance, traditional peritoneal dialysis catheterization includes a longer incision length and a high staining rate often leads to surgical failure; and 4) surgery is more difficult for obese patients. Mandarapu et al. reported[24] that the failure rate of conventional open peritoneal dialysis catheter placement could reach 10.0% to 22.0%. Therefore, accurate intraoperative positioning, fixation and prevention of postoperative infection are important for successful peritoneal dialysis treatment.

Lee et al. reported[25] that 102 patients who received peritoneal dialysis were divided into two groups, receiving either laparoscopic or conventional catheter placement, and were followed up for 6 months after surgery. The results showed that the probability of transabdominal tube displacement and blockage in patients who received traditional laparotomy was 12%. However, no drift or blockage of the peritoneal tube occurred in patients undergoing laparoscopic peritoneal catheterization. There are other reports of laparoscopic PD catheter placement describing excellent results. Ko J et al. reported that the success rate of laparoscopic catheterization was 100%, but in their reports, the incidence of laparoscopic infection was as high as 25%[23]. Other researchers have used stitches to fix the catheter in place during laparoscopy, with reported success rates of 94% to 100%[5, 26]. A study by Ko et al. also showed a favourable outcome when fixing the catheter to the lower abdominal wall. In their report, only 1 late migration (2.6%) of the catheter occurred. Regretfully, patient details were not provided in the study[24].

There are several limitations of our meta-analysis that should be taken into account. First, the information in several studies was incomplete because of the lack of sufficient data, and subgroup analysis based on study type or study region was not conducted. Second, this meta-analysis did not include a large number of RCTs, and the quality of several trials was not high. Follow-up times were different and could have affected our conclusions. Third, as mentioned in the individual studies, the condition and technique of the studies were varied widely. The RCTs in this meta-analysis had key methodological limitations, particularly due to participant attrition and unclear blinding methods, which reduced our confidence in the conclusions drawn from the contributing data. Finally, the inevitable result of these practice trials was that there were so many laparoscopic techniques used by surgeons for catheter placement, and these different catheterization techniques may have affected the final results. Despite these limitations, our results are very meaningful for understanding the differences in outcomes between laparoscopic catheter placement and conventional open surgery catheter placement. These limitations also encourage researchers to design stricter RCTs in the future.

Conclusions

Our meta-analysis demonstrates that compared with conventional open catheterization, laparoscopic catheterization can reduce the occurrence of catheter migration and malfunction. However, laparoscopic catheterization has a higher risk of bleeding than conventional open catheterization, and the higher incidence of bleeding in the laparoscopic group may be due to the fact that the puncture procedure lacks sufficient monitoring of bleeding. Laparoscopic catheterization and conventional open catheter placement in peritoneal dialysis patients have their own advantages, but laparoscopic catheterization may be superior to conventional open catheter placement. Our results will provide a reference for surgeons in choosing a PD catheter placement technique.

Declarations

Acknowledgements

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Compliance with Ethical Standards

The authors have no conflicts of interest to disclose.

Ethics and dissemination: There are no ethical considerations associated with this review. Ethical approval is not required because this protocol does not involve any subjects directly.

Abbreviations

CI = confidence interval, CNKI = China National Knowledge Infrastructure database, ESRD = end-stage renal disease, RCT = randomized controlled trial, RR = risk ratio, PD = peritoneal dialysis, SMD = standard mean difference

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Figures

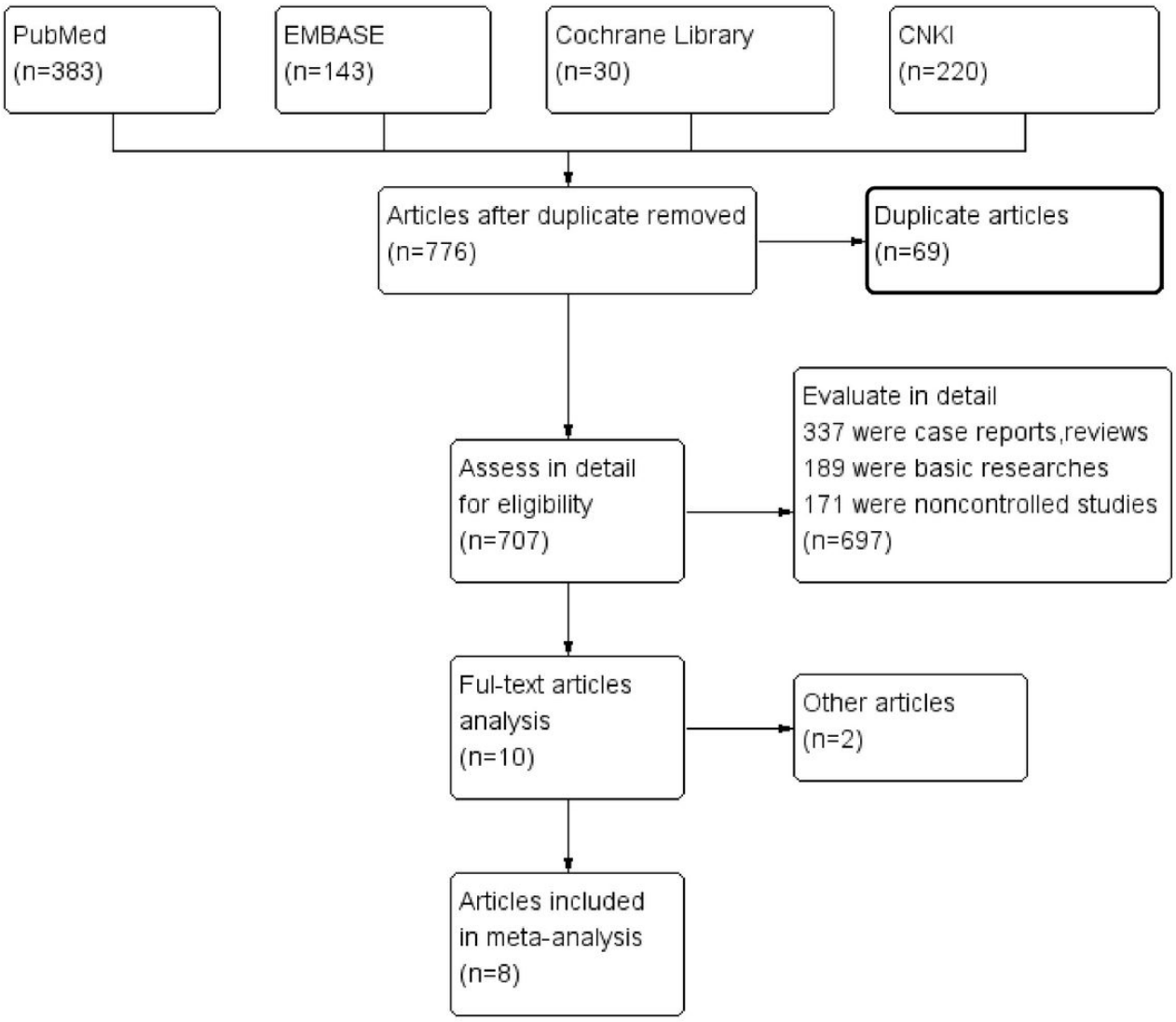

Figure 1

Flow chart of the studies included in the meta-analysis.

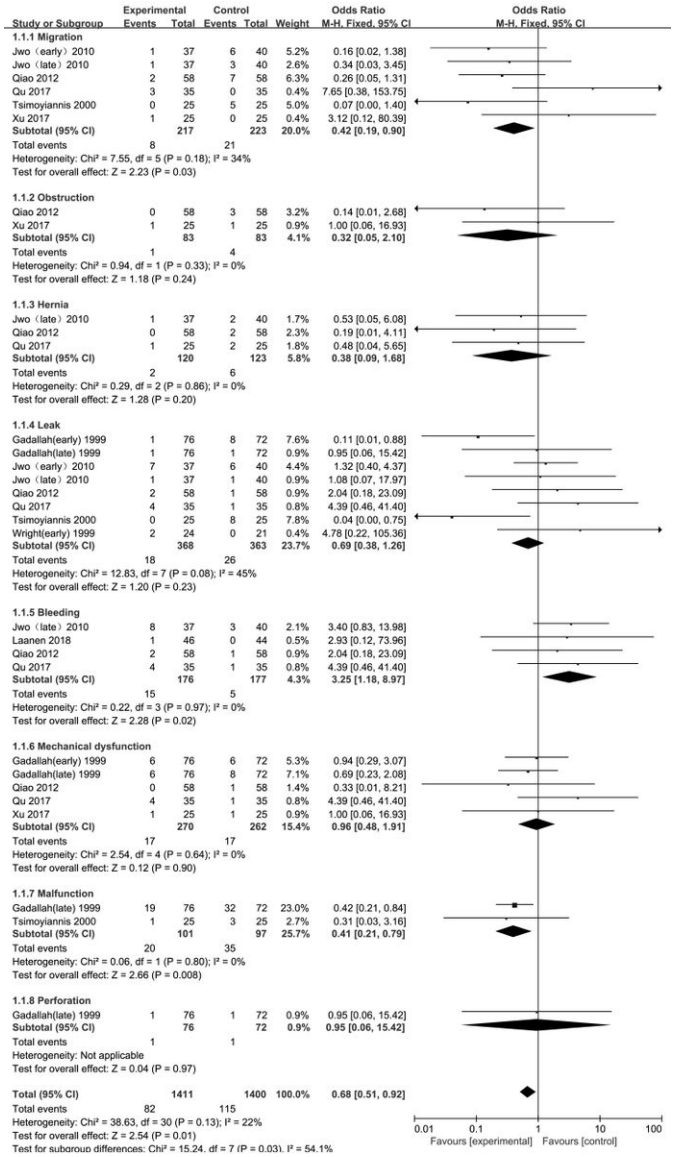

Figure 2

Forest plot of catheter-related complications in observational studies.

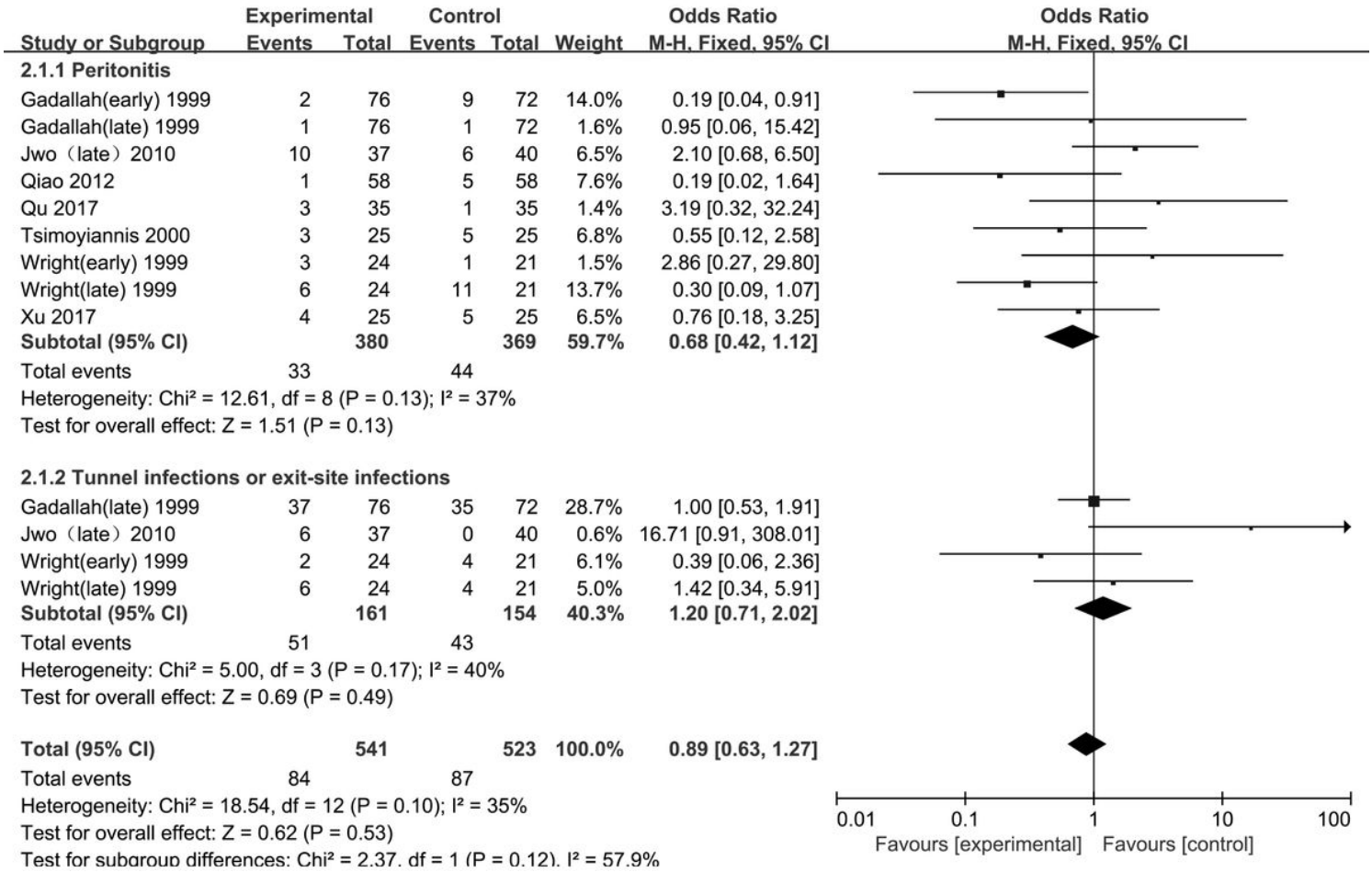

Figure 3

Forest plot of infections in observational studies.

Supplementary Files

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