Hand-assisted laparoscopic vs. mini-laparotomy technique for ventriculoperitoneal shunt.

A meta-analysis of three thousand patients

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BACKGROUND: *Whether or not the laparoscopic technique has substantial advantages over the mini-laparotomy one for ventriculoperitoneal shunt is still controversial.*
The present study is a literature review and a meta-analysis about this topic, focused on the duration of surgery, length of stay (LOS), infection rate and rate of distal catheter failure.
METHODS: *An extensive online literature search was performed, followed by a meta-analysis implemented with RevMan 5.0 Cochrane software. For laparoscopy and mini-laparotomy group, odds ratio (OR) and 95% confidence interval (CI) was calculated for distal catheter malposition/obstruction and infection rate. Mean difference was considered for duration of surgery and LOS. Fixed-effect model with a significance < 0.05 was employed. A t-test ($p< 0.05$) between the groups, also including the non-comparative cohort studies, was performed for each primary endpoint.*
RESULTS: *18 studies, involving 3361 patients, were selected. Average level of evidence was 3.2 ± 0.7. Primary shunts were 93 % in laparoscopy group and 87 % in mini-laparotomy one ($p=0.626$). A previous abdominal surgery was present in 37.5 % and 33.7% of laparoscopy and laparotomy group, respectively ($p=0.449$). Laparoscopy had a lower incidence of distal catheter failure (OR 0.52, 95% CI 0.38–0.72; $p<0.001$). No differences were revealed about the duration of surgery, LOS and infection rate.*
CONCLUSION: *Laparoscopic technique has a lower risk of distal catheter failure in ventriculoperitoneal shunt for the treatment of hydrocephalus. Duration of surgery, LOS and infection rate are independent by the surgical technique. The overall level of evidence is low, and no absolute conclusions can be drawn.*

KEY WORDS: Hand-Assisted Laparoscopy, Hydrocephalus, Meta-Analysis, Mini-Laparotomy, Shunt Failure, Shunt Malfunction, Ventriculoperitoneal Shunt

Introduction

Hydrocephalus is among the most common pathologies affecting the central nervous system, being the consequence of a wide range of congenital and acquired conditions affecting both adulthood and pediatric age. Despite the tremendous evolution and refinement of the surgical techniques aimed to the treatment of hydrocephalus, ventriculoperitoneal (VP) shunt remains still a workhorse [1-6]. Nevertheless, it is burdened by an overall complication rate of 23.8%, which is independent by the cause of the hydrocephalus and typically occurring within the first year [7-11]. Shunt malfunction has been reported to be the most frequent diagnosis of admission at all related to the VP shunt in U.S., with

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an estimated incidence of 40.7% and an average cost of $35,816 [12]. While varying among the series, the rate of distal catheter failure of the standard mini-laparotomy technique has been reported to be the cause of shunt malfunction up to 28.7% of cases [13]. In the last decade, the spectacular improvement and spreading of the general surgery techniques, especially laparoscopic ones, has aroused interest in neurosurgical field about a theoretical lower incidence of distal catheter failure in comparison with the standard mini-laparotomy routinely performed for VP shunt [14-26]. Operative time, post-operative pain, hospital stay, and time to recovery are further key factors to consider in the comparison. To date, however, most of the literature on this topic consists of retrospective observational cohort studies having a consequent level of evidence too much low to draw definitive conclusions. Heterogeneity of the studies population, lacking of control groups, introduction of technical notes, frequent missing of data about duration of surgery, infection rate and length of stay (LOS), and not sufficiently long follow-ups are further biasing factor affecting the interpretation of the results of both techniques, at the same time raising the need for randomized clinical trials (RCTs) and meta-analysis.

The present study consists in a literature review and meta-analysis about the laparoscopic vs. mini-laparotomy technique for the positioning of distal catheter of the VP shunt in the treatment of adult hydrocephalus.

The primary endpoints of the study have been to evaluate whether or not the hand-assisted laparoscopic technique was associated with a lesser duration of surgery, a shorter LOS, and had a lower rate of infection and distal catheter malposition.

Methods

An online literature search was performed with the PubMed/MEDLINE (https://pubmed.ncbi.nlm.nih.gov), EMBASE (https://www.embase.com/login) and Cochrane Library (https://www.cochranelibrary.com) databases. The Medical Subject Heading (MeSH) was used, where the MeSH terms "Hydrocephalus", "Ventriculoperitoneal Shunt" "Hand-Assisted Laparoscopy" and "Laparotomy" were combined together. For each MeSH term, the search was restricted to the subheading "therapy". A further free text search was conducted, which involved the combination of the same terms and, in addition, "hydrocephalus" [text word], "catheter placement" [text word], "complications" [text word], "infection" [text word], "duration of surgery" [text word] and "length of stay" [text word]. A further sorting was carried out based on the best match and relevance inferred by the titles and abstracts. The studies identified were screened for the eligibility having as inclusion criteria all the relevant articles in English, or translated from English, with a number of cases > 10. No time restriction was applied. Studies involving the pediatric age, technical notes regarding the laparoscopic placement of the peritoneal catheter, series involving the use of laparoscopic technique only for the management of shunt complications and editorials were excluded. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) criteria were used [27].

The meta-analysis of the comparative studies was performed using the software RevMan 5.0 (Cochrane Informatics & Knowledge Management Department).

Odds ratio (OR) with 95% confidence interval (CI) for the dichotomic variables "distal catheter malposition/obstruction rate" and "infection rate" were calculated for "laparoscopic technique" group vs. "mini-laparotomy technique" one, whereas mean difference was considered for the continuous variables duration of surgery and LOS. Fixed-effect model with a significance < 0.05 was employed. OR of each endpoint was reported as Forest plot. I^2 heterogeneity test of the studies was performed assuming a value < 25%, ranging between 25% and 50% and > 50% as expression of a low, moderate and high heterogeneity, respectively. Heterogeneity related to the different endpoints was reported as Funnel plot.

Additionally, a t-test (2 tails, paired samples, unequal variance) between the laparoscopy and mini-laparotomy group, involving comparative and non-comparative studies, was performed for the same parameters. P value was set at < 0.05.

Results

Literature Volume

The search initially retrieved 162 articles. After the removal of duplicates and screening, 46 articles were assessed for eligibility. The further refinement. Of the search and the application of the exclusion criteria led to select 18 studies to be included in the qualitative synthesis.

Figure 1 reports the PRISMA flow chart employed for the literature review (Fig. 1).

Eleven studies were comparative, of which 3 rcts (level of evidence II) and 15 retrospective observational (level of evidence III and IV in 11 and 7 patients, respectively). Seven studies were case series focused only on laparoscopic technique. Mean follow-up was 21.4 ± 15.3 months in laparoscopy group and 19.2 ± 6.7 months in laparotomy one. Average level of evidence was 3.2 ± 0.7. Graph 1 and 2 report the percentage of rcts and observational studies in laparoscopy and laparotomy group, respectively (Graph 1, 2).

Demographic and Clinical Data

A total of 3361 patients belonging to 18 studies were included in quantitative synthesis. Average patients' age

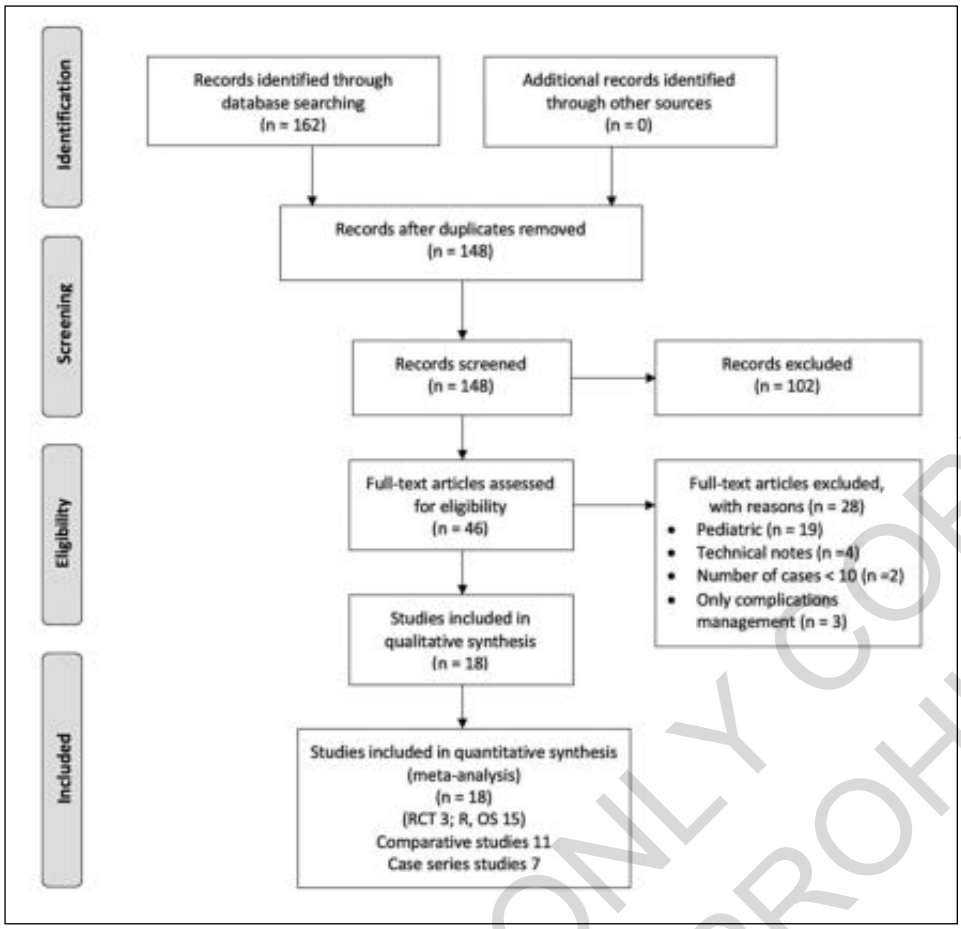
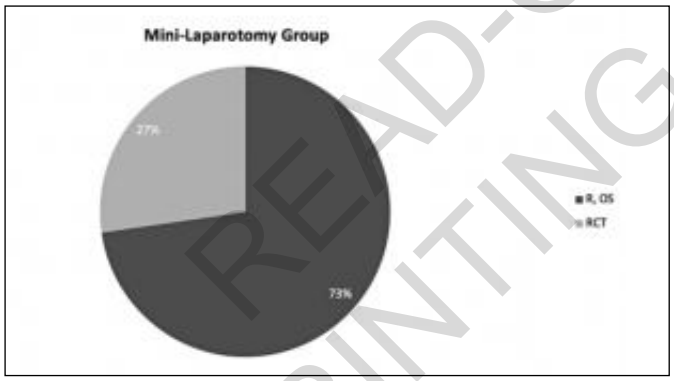
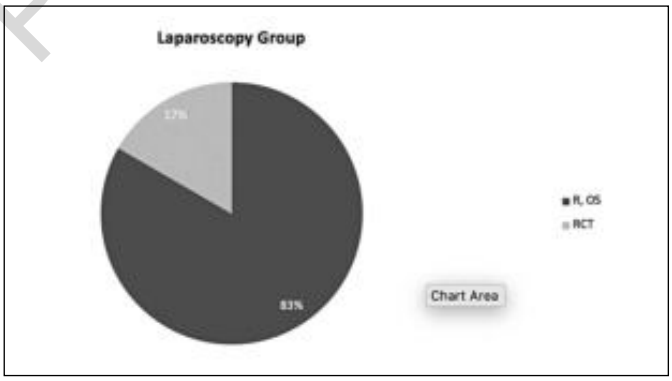


Fig. 1: PRISMA flow chart of literature search strategy.



Graph 1: Percentage of RCTs and observational studies in laparoscopy group.



Graph 2: Percentage of RCTs and observational studies in mini-laparotomy group.

was 57.4 ± 6 (41-66) and 55.2 ± 7 (37-63.6) years in laparoscopy and mini-laparotomy group, respectively. Male/female ratio was 0.9 in laparoscopy group and 0.8 in mini-laparotomy one.

Primary shunts were 93 % and 87 % of the laparoscopy and laparotomy group, respectively. 37.5 % and 33.7% of patients of laparoscopy and laparotomy group, respectively had a previous abdominal surgery for reasons other than VP shunt. No differences were found between the groups about the amount of revision surgeries and previous abdominal surgeries (t-test, 2 tails, unpaired samples; p=0.626 and p=0.449, respectively). Table I summarizes the demographic and clinical data of the main studies on laparoscopic and mini-laparotomy technique (Table I)

Duration of Surgery

Average duration of surgery was 47.5 min in laparoscopy group and 63.5 min in laparotomy one. The analysis of 3 comparative studies [28-30] reporting this data showed a

TABLE I - *Studies on Laparoscopic and Mini-Laparotomy Technique*

Author/Year	Study type	Level of Evidence	N. of patients		Primary y shunt (n)		Revision n. Surgery y(n)		Previous s abdominal surgery (n)		Duration of Surgery (average min)		Length of Stay average days)		Distal Catheter Malposition /Obstruction (n.)		Infections (n.)		Follow -up (average months)
			L	ML	L	ML	L	ML	L	ML	L	ML	L	ML	L	ML	L	ML	
Schievink, 1993	R, OS	IV	10	-	10	-	0	-	0	-	NA	-	NA	-	0	-	0	-	12
Cautico, 1995	R, OS	III	11	11	11	11	0	0	NA	NA	NA	NA	NA	NA	0	2	0	0	12
Reimer, 1998	R, OS	IV	53	-	NA	-	NA	-	NA	-	50 (median)	-	NA	-	NA	-	NA	-	29
Khaitan, 1999	R, OS	IV	10	-	10	-	0	-	2	-	42,5	-	1,5	-	0	-	0	-	18
Kirshtein, 2004	R, OS	IV	24	-	16	-	8	-	16	-	63	-	8,2	-	1	-	1	-	17,8
Schubert, 2005	P, RCT	II	50	50	37	39	13	11	25	22	59	49	NA	NA	3	12	1	6	11
Bani, 2006	R, OS	III	151	50	NA	NA	NA	NA	NA	NA	47,5	45	NA	NA	0	4	2	1	NA
Tepetes, 2006	R, OS	IV	10	-	10	-	0	-	8	-	NA	-	4	-	0	-	0	-	NA
Roth, 2007	R, OS	III	59	152	43	134	16	18	15	18	NA	NA	NA	NA	4	15	8	11	22
Argo, 2009	R, OS	III	258	321	215	283	43	38	106	96	37,5	52	11	14	15	18	24	24	13,5
Sekula, 2009	R, OS	IV	66	-	NA		NA		NA	-	55,3	-	5,85	-	0	-	0	-	19
Park, 2010	R, OS	III	95	65	NA	NA	NA	NA	NA	NA	52	109	NA	NA	0	2	2	2	27
Naftel, 2011	R, OS	III	475	335	401	298	74	37	200	113	43,5	55,6	8,5	11,9	25	36	39	22	12
Raysi Dehcordi, 2011	R, OS	III	30	30	11	23	19	7	13	11	30	62,5	NA	NA	1	5	0	0	13
Cohen-Inbar, 2014	RCT	II	40	248	NA	NA	NA	NA	NA	NA	NA	NA	12,3	14,1	6	32	6	33	NA
Nigim, 2014	R, OS	III	155	77	155	77	0	0	37	23	43,7	63	5	5	4	2	0	2	32,6
Schucht, 2014	RCT	II	60	60	57	11	3	1	22	17	63,9	72,2	9,6	8,9	0	5	1	3	12
Alyeldien, 2018	R, OS	IV	405	-	341	-	64	-	NA	-	30	-	NA	-	0	-	15	-	70,8

R, OS: retrospective observational study; RCT: randomized controlled trial; L: laparoscopic technique; ML: mini-laparotomic technique; NA: not available.

TABLE II - *T-Test Comparison of Laparoscopic vs. Mini-Laparotomy Technique*

Study Endpoint	LaparoscopicTechnique	Mini-laparotomy Technique	P value*
Duration of Surgery (average min.)	47.5	63.5	0.069
Length of Stay(average days)	7.3	10.8	0.137
Infections(average n.)	5.8	9.5	0.414
Distal Catheter Malposition/Obstruction (average n.)	3.5	12.1	0.049

* $p < 0.005$

significant difference between the 2 groups in favor of laparoscopy (mean difference [MD] -13.65, 95% CI -16.13 to -11.17; $p < 0.001$). Graph 1 reports the Forest plot for the primary outcome duration of surgery (Graph 3). I^2 was 70% (Graph 4). The extension of the analysis also to the observational studies [31-35] by means of the t-test did not confirmed the difference between the 2 groups (p=0.069) (Table II).

Length of Stay

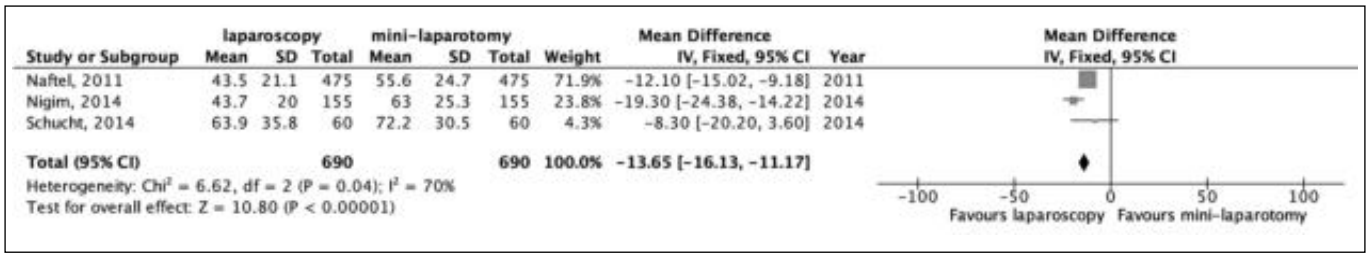
Mean LOS was 7.3 ± 3.5 in laparoscopy group and 10.8 ± 3.9 in mini-laparotomy group. No difference was found between the groups in 3 comparative studies [28-30] (MD -0.51, 95% CI -1.81 to 0.70; p=0.44) (Graph 5). I^2 was 51% (Graph 6). Similar data were found on t-test where 4 further cohort studies were involved (p=0.137) [32-34, 36] (Table II).

Infection Rate

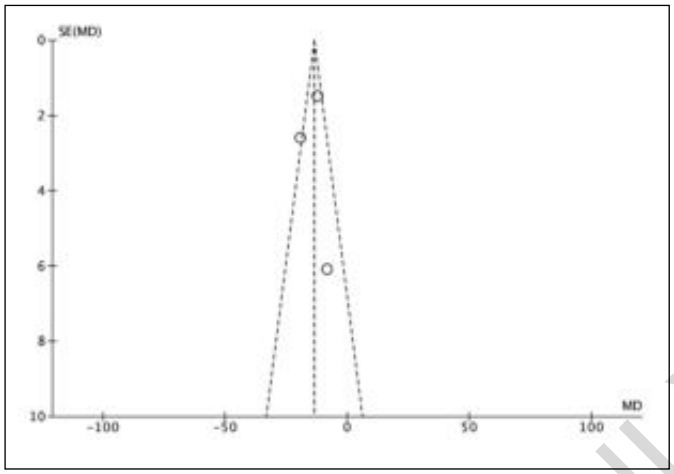
Average number of infections was 5.8 ± 10 and 9.5 ± 11 in laparoscopy and mini-laparotomy group, respectively. The overall infection rate, evaluated on 9 studies [28-30, 37-42], was 5.8% in laparoscopy group and 6.3% in laparotomy group. Difference was not significant (OR 1.09, 95% CI 0.78–1.53; p=0.62) (Graph 7). I^2 was 24% (Graph 8). The inclusion of 6 cohort studies [32-36, 43] in t-test led to similar data (P=0.414) (Table II).

Rate of Distal Catheter Malposition/Obstruction

The overall rate of distal catheter malposition/obstruction was 4.1% and 9.5% in laparoscopy and laparotomy group, respectively. This difference was significant (OR 0.52, 95% CI 0.38–0.72; p<0.001) (Graph 9), with



Graph 3: Forest plot for duration of surgery.



Graph 4: Funnel plot for duration of surgery.

an estimated I^2 among the 11 considered studies of 40% [28-30,37-42, 44, 45] (Graph 10). T-test confirmed the existence of a difference on further 6 studies in addition to the comparative ones [32-36, 43] (p=0.049) (Table II).

Discussion

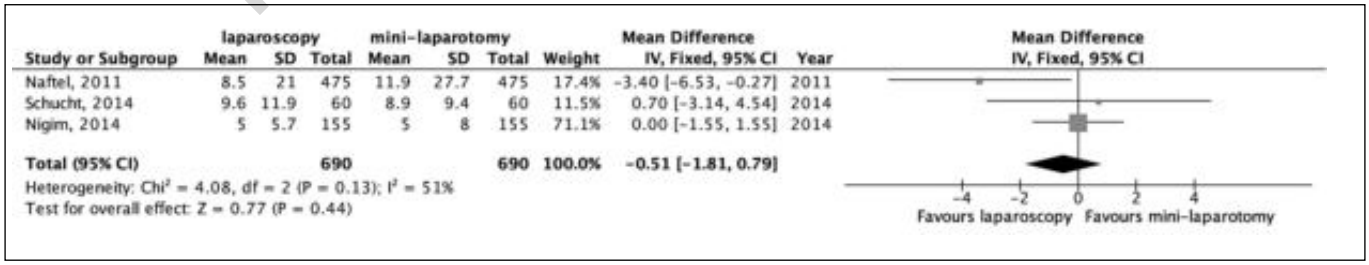
The present study was aimed at assessing whether or not the hand-assisted laparoscopic technique for the insertion of the distal catheter of the VP shunt is advantageous in comparison with the mini-laparotomy technique for what concern specific endpoints, namely the duration of surgery, LOS, infection rate and distal catheter malposition.

The difficulty in the distal catheter placement especially in obese patients, but also in a wider presumed heterogeneity regarding the etiology of the hydrocephalus in this age group.

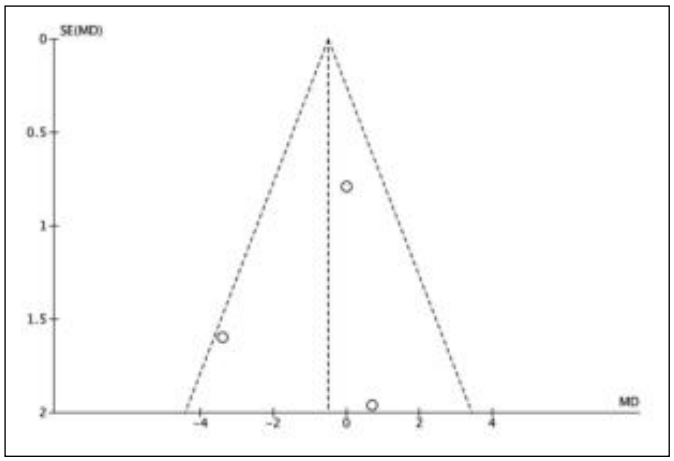
The present meta-analysis was based on an average level of evidence of 3.2 ± 0.7, encompassing only 3 RCTs having a number of patients ranging between 40 and 60. Most of the remaining articles, although involving larger cohorts, basically were case-control studies. For comparative studies, I^2 ranged between 24% and 70% with a median of 46.2%.

As a consequence, the overall heterogeneity of the studies included in the quantitative synthesis should be considered not sufficietly high to draw definitive conclusions.

To the best of our knowledge, only 2 meta-analysis have been reported in literature until now [46, 47]. The first one was performed by Phan et al. in 2015, where they found no differences between the mini-laparotomic and laparoscopic approaches concerning the LOS, complication rate, proximal shunt failure and infection rate [47]. In contrast, they found laparoscopic technique to be linked with a reduced shunt failure and a decreased rate of abdominal malposition. Noteworthy, they included 10 comparative studies, of which only 2 RCTs, and the reported I^2 was up to 89% with a consequent very high risk of bias. The second meta-analysis by He and colleagues in 2016 concluded that, to some extent, the laparoscopic technique is associated with a lower distal failure rate, a shorter operative time and a reduced blood loss [46]. Three important aspects however affect the interpretation of the results of this last study. First, with the exception of 2 RCTs, the meta-analysis was restricted only to case-control series, this point limiting the contribution of a non-negligible number of observational studies especially in the assessment of the complications rate. Second, for almost all of the seven outcomes



Graph 5: Forest plot for length of stay.

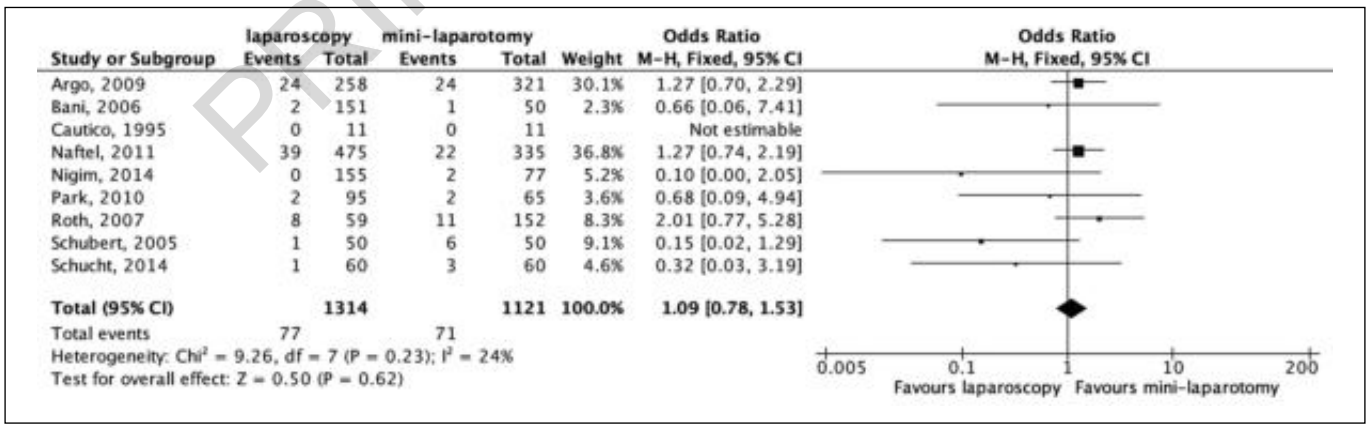


Graph 6: Funnel plot for length of stay.

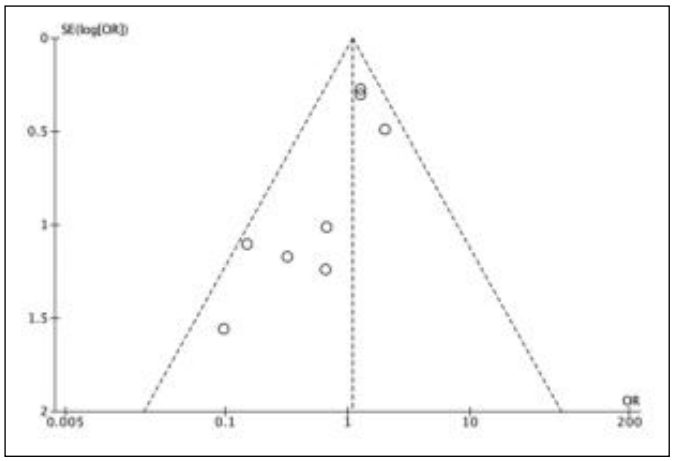
assessed the quality of evidence was low to very low because of the equally low level of evidence of the included studies. Third, the study had an undefined risk of bias, potentially by far higher than that admitted, which was calculated on the basis of only 2 articles [29, 48].

Data of our meta-analysis led to conclude that, in comparison with mini-laparotomic one, hand-assisted laparoscopic technique is certainly associated with a lower risk of distal catheter malposition/obstruction. Similar conclusions have been reported in the meta-analysis from Phan and He, and in several other case-control studies [28,29,35,41,42,44,46]. These findings may lie in the direct, magnified and clearer visualization of the distal part of the catheter deriving from the introduction of the endoscope into the operative field. The same advantages related to the look around the corner visualization of the surgical target have been already reported for many other neurosurgical pathologies [49-54]. Naftel and Roth suggest a role of laparoscopy also in allowing a useful adhesiolysis, especially in those patients underwent to a previous abdominal surgery [28, 41]. Interestingly, specific genetic phenotypes are responsible of a higher rate of spontaneous and post-surgical peritoneal adhesions [55-59]. Furthermore, laparoscopy seems to cause less peritoneal inflammation with a reduced likelihood of formation of adhesions [60].

Conversely, LOS and infection rate are independent from the technique used. Especially for infections, the difference was slightly in favor of laparotomy. Very close to the significance in favor of the laparoscopic technique was the duration of surgery, leading to assume that further trials on larger sample size cohorts may reveal some advantages. Duration of surgery is highly variable among the studies, ranging between 42 to 81 min for laparoscopy, and 49 to 116 min for mini-laparotomy [31,32,41,42,60-62]. Nevertheless, Phan et al. reported in their meta-analysis a trivial average difference between the 2 techniques, namely about 10 min. It should be also considered that the duration of surgery tends to vary significantly among the studies by the reasons of the fact that, technically, some authors prefer to perform contemporarily the cranial and abdominal stage of the operation. Whether or not this aspect may also affect the rate of infection has still to be assessed, although, to our knowledge, no conclusive data in this sense are present in literature. The likelihood of infection is instead undoubtedly to be put in relation to several other factors, as the body mass index, patient's comorbidities and different schemes of antibiotic prophylaxis, just to name a few. Body mass index in particular is known to be associated with a higher rate of infections but also other several complications in neurosurgery [63]. LOS is a further factor severely conditioned by the cause of hydrocephalus, and for which it results difficult to reach definitive conclusions in the absence of a randomization aimed at the elimination of this biasing factor. In the present study, the number of revisions and previous abdominal surgeries was the same in the 2 study groups, allowing to assume that these factors do not have had interferences with the results. However, Argo et al. report that both were predictors of complications for mini-laparo-



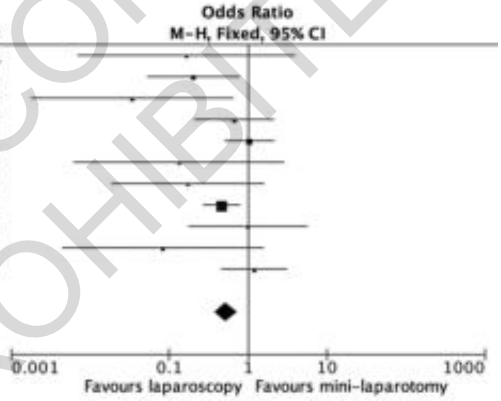
Graph 7: Forest plot for overall infection rate.



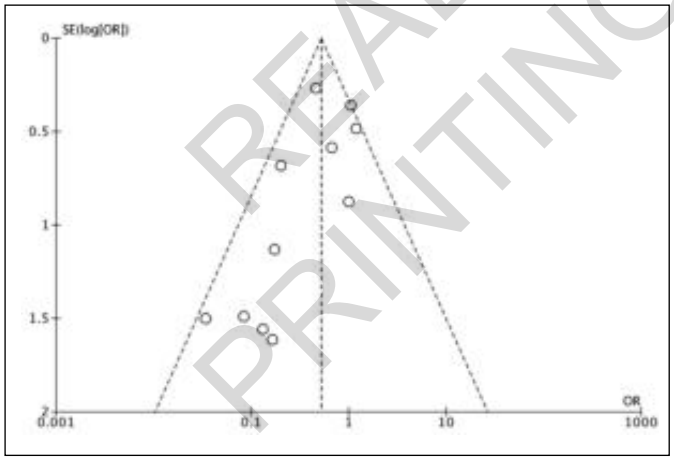
Graph 8: Funnel plot for overall infection rate.

Study or Subgroup	laparoscopy Events	Total	mini-laparotomy Events	Total	Weight	Odds Ratio M-H, Fixed, 95% CI	Year
Cautico, 1995	0	11	2	11	2.2%	0.17 [0.01, 3.88]	1995
Schubert, 2005	3	50	12	50	10.6%	0.20 [0.05, 0.77]	2005
Bani, 2006	0	151	4	50	6.3%	0.03 [0.00, 0.65]	2006
Roth, 2007	4	59	15	152	7.3%	0.66 [0.21, 2.09]	2007
Argo, 2009	15	258	18	321	14.2%	1.04 [0.51, 2.10]	2009
Park, 2010	0	95	2	65	2.8%	0.13 [0.01, 2.82]	2010
Raysi Dehcordi, 2011	1	30	5	30	4.5%	0.17 [0.02, 1.58]	2011
Naftel, 2011	25	475	36	335	37.5%	0.46 [0.27, 0.78]	2011
Nigim, 2014	4	155	2	77	2.4%	0.99 [0.18, 5.55]	2014
Schucht, 2014	0	60	5	60	5.1%	0.08 [0.00, 1.54]	2014
Cohen-Inbar, 2014	6	40	32	248	7.1%	1.19 [0.46, 3.06]	2014
Total (95% CI)		**1384**		**1399**	**100.0%**	**0.52 [0.38, 0.72]**	
Total events	58		133				

Heterogeneity: $Chi^2 = 16.53$, df = 10 (P = 0.09); $I^2 = 40\%$
Test for overall effect: Z = 3.96 (P < 0.0001)



Graph 9: Forest plot for distal catheter failure.



Graph 10: Funnel plot for distal catheter failure.

tomy [37]. Similar results have been reported by Schubert et al and Turner et al [42, 61]. Considering the minimal invasiveness of both the surgical techniques considered, we believe that the estimation of the differences in terms of blood loss doesn't have a rationale.

Study Caveats

The present study has some important constraints. First, its intrinsic retrospective feature based upon a limited number of surgical series, most of which with a high number of patients coming from a single center, unavoidably increases the risk of bias. Second, the body mass index has not been reported because not available for most of the studies. Nevertheless, at least theoretically, the greater the body mass index, the greater the technical difficulty in the positioning of the distal catheter, the higher the incidence of complications. Third, the causes of hydrocephalus have not been reported, this last being a further potential bias. Fourth, we should admit that the inhomogeneity of surgical teams, involving neurosurgeons and general surgeons may have conditioned the results.

This last aspect is known to affect the outcome evaluation similarly to what already reported for different other neurosurgical pathologies involving a multidisciplinary approach [64-67].

Further prospective multi-center RCTs are needed to validate our results.

Conclusion

Hand-assisted laparoscopic technique has a lower risk of distal catheter malposition/obstruction in VP shunt for the treatment of hydrocephalus. LOS and infection rate are not affected by the surgical technique.
Duration of surgery, although not statistic and severely conditioned by the high heterogeneity of the reported studies, is slightly in favor of laparoscopic technique, but the average difference is however trivial.
The overall level of evidence of the included studies is low on the whole, to the point that no definitive conclusions can be drawn.

Acknowledgments

We want to thank Eng. Giorgia Di Giusto for her outstanding and valuable support in formatting the manuscript and editing the graphs and figures.

Riassunto

È ancora controverso se la tecnica laparoscopica abbia sostanziali vantaggi rispetto a quella mini-laparotomica nello shunt ventricolo-peritoneale.
Il presente studio consiste in una revisione della letteratura e una meta-analisi su questo argomento, fondamentalmente incentrata sulla durata dell'intervento chirurgico, durata della degenza, tasso di infezioni e tasso di malfunzionamento/ostruzione del catetere distale.
È stata eseguita un'ampia ricerca online della letteratura, seguita da una meta-analisi mediante l'ausilio del software Cochrane RevMan 5.0. Per il gruppo di laparoscopia e mini-laparotomia è stato calcolato l'odds ratio (OR) e l'intervallo di confidenza al 95% (CI) relativi a tasso di malfunzionamento/ostruzione del catetere distale, e tasso di infezione. La differenza media è stata invece analizzata relativamente alla durata dell'intervento chirurgico e al tempo di degenza. È stato impiegato un modello a effetto fisso con un livello di significatività p<0.05. Per ciascun endpoint primario è stato inoltre eseguito un test t (p <0,05) tra i gruppi, inclusi anche gli studi di coorte non comparativi.
Sono stati selezionati 18 studi, che hanno coinvolto in totale 3361 pazienti. Il livello medio di evidenza è stato 3,2 ± 0,7. Gli shunt primari erano 93% nel gruppo laparoscopico e 87% in quello mini-laparotomico (p = 0,626). Un precedente intervento chirurgico addominale era presente nel 37,5% e 33,7% del gruppo laparoscopico e laparotomico, rispettivamente (p = 0,449). La laparoscopia ha avuto una minore incidenza di fallimento (malfunzionamento/ostruzione) del catetere distale (OR 0,52, IC 95% 0.38-0.72; p <0,001). Non sono state rilevate differenze relative alla durata dell'intervento chirurgico, tempo di degenza e tasso di infezioni.
La tecnica laparoscopica presenta un minor rischio di fallimento del catetere derivativo distale nello shunt ventricolo-peritoneale eseguito per il trattamento dell'idrocefalo. La durata dell'intervento chirurgico, il tempo di degenza e il tasso di infezioni sono indipendenti dalla tecnica chirurgica. Il livello complessivo di evidenza degli studi è basso, non essendo possibile al momento trarre conclusioni assolute.

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