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Review Article

Standard and restrictive fluid regimen in major abdominal surgery: a meta-analysis of RCTs

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Abstract: *Background:* To compare the effect of restrictive fluid regimen (RFR) and standard fluid regimen (SFR) in major abdominal surgery. *Methods:* We searched relational randomized controlled trials (RCTs) from databases which included PubMed, Cochrane, and EMBASE until February 2019. Review Manager 5.3 software was used to conduct this study. We conducted publication bias evaluation, quality assessment and subgroup analysis at the same time. *Results:* In total, 4945 patients were enrolled in 16 RCTs. The SFR had higher incidence of pulmonary infection (RR: 0.68, 95% CI: 0.52~0.90, P = 0.007, I^2 = 1%). Psychosis disorders (RR: 0.53, 95% CI: 0.29~0.97, P = 0.04, I^2 = 0%) were more likely to occur in SFR. However, the RFR had high incidence of renal dysfunction (RR: 1.49, 95% CI: 1.16~1.90, P = 0.02, I^2 = 36%). The effect of the two regimens in postoperative anastomotic leakage (RR: 0.96, 95% CI: 0.69~1.35, P = 0.83, I^2 = 32%) and the length of hospital stay (SMD: -0.21, 95% CI: -0.64~0.22, P = 0.34, I^2 = 96%) had no statistical difference. *Conclusion:* The perioperative RFR was superior to SFR in reducing pulmonary infection and psychosis disorders after major abdominal surgery, but also had a higher risk of renal dysfunction.

Keywords: Fluid regimen, major abdominal surgery, postoperative complications

Introduction

Patients after general surgery may experience complications, with a probability of 5.8% to 43.5% [1], and postoperative pulmonary complications (PPCs) are the most harmful [2, 3]. Almost all operations require perioperative fluid regimens which intend to maintain optimal oxygen supply and adequate tissue perfusion [4].

SFR assists with compensatory intravascular volume expansion, physiological requirements, loss of blood, preoperative fasting, redistribution of the third space, and the total volume given to patients on the day of surgery is often more than 5 liters [5-8]. However, Gustafsson [9] found that the perioperative fluid regimen was an independent predictor of clinical efficacy, and every additional 1 liter of intravenous infusion could, respectively 16% and 32%, increase the risk of delayed recovery after general anesthesia and complications after surgery. On the other hand, RFR pursues a net balance, and the total volume of fluids given on surgery day is usually no more than 3 liters [5-8], which is close to the idea of an Enhanced Recovery after Surgery (ERAS) that brings less postoperative complications and shorter hospital stays [10, 11]. Another two meta-analyses [12, 13] both recommend RFR when undergoing major abdominal surgery. Recently, these conclusions have been impacted by Myles' multicenter and large sample randomized controlled trials [5].

In view of this, this study will be an update to give the highest level evidence for best clinical treatment by analyzing published RCTs about standard and restrictive fluid regimens in major abdominal surgery.

Methods

This meta-analysis was carried out in accordance with PRISMA guidelines [14]. Major abdominal surgery was the subject of our study. Interventions were restrictive fluid regimen versus standard fluid regimen. Outcomes included postoperative complications and length of hospital stay. The study type is RCT.

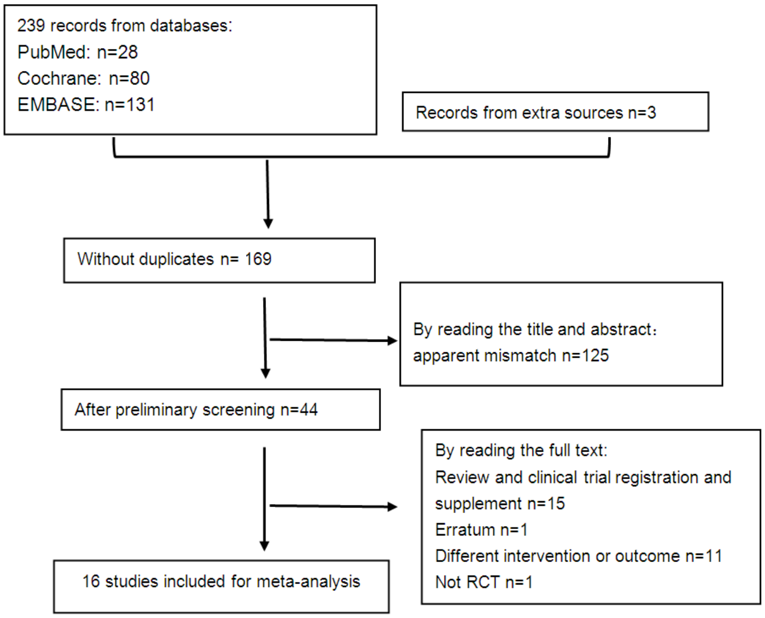

Figure 1. Flow diagram for selection.

Literature search and selection

The key words included were; liberal/standard/conventional and restrictive/restriction fluid therapy/management/regimen/administration and major surgery/abdominal surgery/bowel surgery/esophagectomy/gastrectomy/pancreatectomy/colectomy/colorectal surgery/nephrectomy/cystectomy/open prostatectomy/hysterectomy/and hepatectomy. We searched PubMed, Cochrane, and EMBASE up until February 2019 and without language restriction. The following criteria were followed when screening literatures. Inclusion criteria: RCTs, restrictive or standard fluid regimen conducted during perioperative periods separately, postoperative complications, and the length of hospital stay were recorded in the outcomes. Exclusion criteria: non-RCTs, fluid regimens have not been performed during the operation time, extra independent interventions.

Potential articles were screened by skimming the title and abstract. Then two authors then selected qualified studies by reading the whole article. Any controversial divergences would be replaced by consensus results, which were counseled by a third professional party.

Data extraction and quality assessment

The following data were extracted from the qualified studies; first author, year of publication, surgery types, interventions, number of patients, age, sex ratio, fluid regimen during operation, length of operation, and outcomes.

The Cochrane Collaboration's tool was used to conduct quality assessment. Publication bias was evaluated by drawing funnel plots.

Outcome measures

The main outcome of this study was pulmonary infection. Postoperative psychosis disorders, renal dysfunction, anastomotic leakage and length of hospital stay were secondary outcomes.

Statistical analysis

Review Manager 5.3 software was used for quality assessment, data processing, forest and funnel plot mapping. If continuous variables were recorded by the median, the method of Hozo [15] would be used to convert them to the form of mean and standard deviation ($\bar{X} \pm S$). First of all, *Q* test and I^2 statistics were used for heterogeneity (test level: $P = 0.10$). If $P \geq 0.10$, $I^2 < 50\%$, indicated that the inclusion studies had homogeneity, and a fixed effect model would be used to calculate the combined statistics. On the other hand, if $P < 0.10$, $I^2 \geq 50\%$, this showed that there was heterogeneity in the included studies. The combined statistics would be calculated by a random effect model, and the subgroup analysis was actualized. The Relative Risk (RR) was chosen as a binary variable to calculate the effective quantity, and the standard mean difference (SMD) for continuous variable. We calculated the corresponding 95% confidence interval (CI) at the same time.

Results

Search results and quality assessment

We found 242 possible articles through the databases and other resources. After eliminating 73 duplicates, we skimed the titles and abstracts and had 44 potential studies. After further reading of the full texts, we selected 16 qualified RCTs [5-8, 16-27], which included

Table 1. Features summarized from qualified RCTs

Author (year)	Intervention	Age (year*)	Male (%)	No.	Surgery time (h)*	Total volume in surgery day*	Intraoperative fluid regimen
Abraham (2012)	Standard	69.0	54.9	82	unclear	5775	Ringer acetate solution, 5 ml/kg/h during surgery, and Buffered glucose 2.5% 2 ml/kg/h;
	Restricted	68.0	54.4	79		3050	Buffered glucose 2.5% 2 ml/kg/h
Brandstrup (2003)	Standard	69	51.4	72	3	5388	Preloading: 500 ml HAES 6%, Third space loss: 0.9% NS 7 ml/kg/h for 1st h, 5 ml/kg/h for 2nd and 3rd h, 3 ml/kg/h;
	Restricted	64	47.8	69	3	2740	No preloading and no third space loss replacement
Gao (2012)	Standard	73	57.0	86	3	3050	Preload 500 mL 6% HAES followed by 12 mL/kg/h RL;
	Restricted	72	58.1	93	3	1555	7 mL/kg RL in first hour, 5 mL/kg/h RL in following hours
Grant (2016)	Liberal	65	47	164	3.28	6077	12 ml/kg/h;
	Restricted	65	58.4	166	3.43	3618	6 ml/kg/h
Holte (2007)	Liberal	76.5	56.2	16	2.14	5050	18 ml/kg/h RL;
	Restricted	73.5	37.5	16	2.14	1640	7 ml/kg/h RL first hour, 5 ml/kg/h RL subsequent hours
Jie (2014)	Standard	65.4	58.3	96	2.57	3110	Preload 500 mL 6% HAES, 12 mL/kg/h RL During the operation;
	Restricted	64.7	56.2	89	2.43	1620	7 mL/kg RL in first hour; 5 mL/kg per hour RL in following hours
Kalyan (2013)	Standard	70	50.4	119	2.42	3315	1.5 ml/kg/h, preload 500 ml Hartmann's solution, third-space losses 7 ml/kg/h for the first hour followed by 5 ml/kg/h;
	Restricted	70	52.7	121	2.68	1944	1.5 ml/kg/h
Kassim (2016)	Liberal	65.8	unclear	25	4.03	4506	12 ml/kg/h;
	Restricted	66.8		25	4.06	2438	4 ml/kg/h
Lobo (2002)	Standard	58.9	60	10	unclear	5700	1 L 0.9% saline and 2 L 5% dextrose;
	Restricted	62.3	80	10		3100	0.5 L 0.9% saline and 1.5 L 5% dextrose, or 2 L 4% dextrose
McArdle (2009)	Standard	75	84.6	11	2.36	6472	Preload 10 mL/kg followed by12 mL/kg/h;
	Restricted	74	90.9	10	2.73	4652	4 mL/kg/h
Muller (2009)	Standard	59	53.3	75	2	5200	preoperative 2 mL/kg/h; intraoperative 10 mL/kg/h;
	Restricted	62	48.7	76	2.33	2700	preoperative 1 mL/kg/h, intraoperative 5 mL/kg/h
Myles (2018)	Liberal	66	51.7	1493	3.3	6146	Bolus 10 ml/kg, followed by 8ml/kg/h;
	Restricted	66	52.4	1490	3. 3	3671	Bolus of no more than 5 ml/kg, followed by 5 ml/kg/h
Nisanevich (2005)	Standard	59.4	53.3	75	4.2	3878	Bolus of 10 ml/kg followed by 12 ml/kg/h;
	Restricted	62.8	49.4	77	4.47	1408	4 ml/kg/h
Peng (2013)	Standard	63	54.4	90	3	6000	Preload 500 mL HAES 6%, Ringer's solution: 12 mL/h/kg;
	Restricted	62	53.6	84	3	3200	Ringer's solution: 7 mL/h/kg first hour; followed by 5 mL/h/kg
Petricevic (2015)	Standard	69.3	86.7	30	2.40	5017	15 ml/kg/h;
	Restricted	68.6	73.3	30	2.03	4039	10 ml/kg/h
Van (2015)	Standard	Unclear	Unclear	32	4.13	3400	10 ml/kg/h;
	Restricted			34	4.82	2100	5 ml/kg/h

*represents mean.

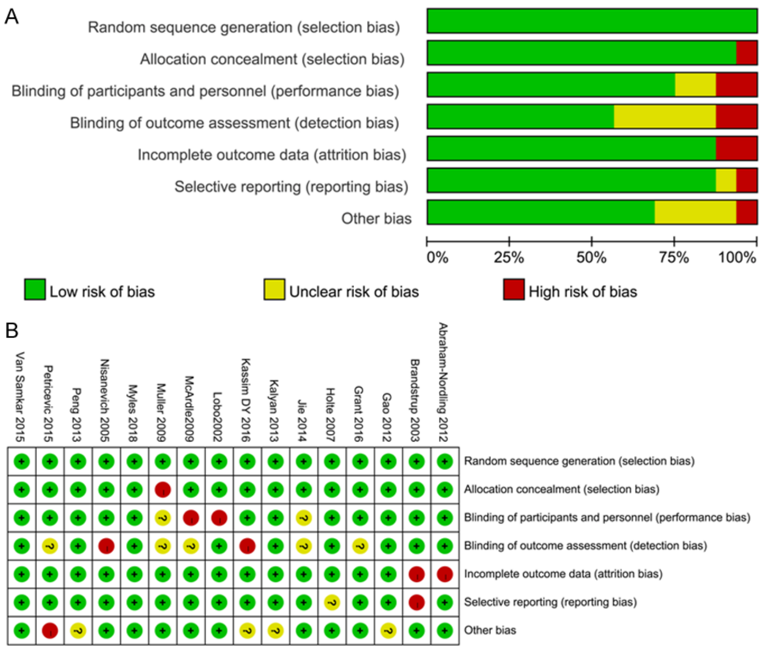

Figure 2. A: Risk of bias graph; B: Risk of bias summary.

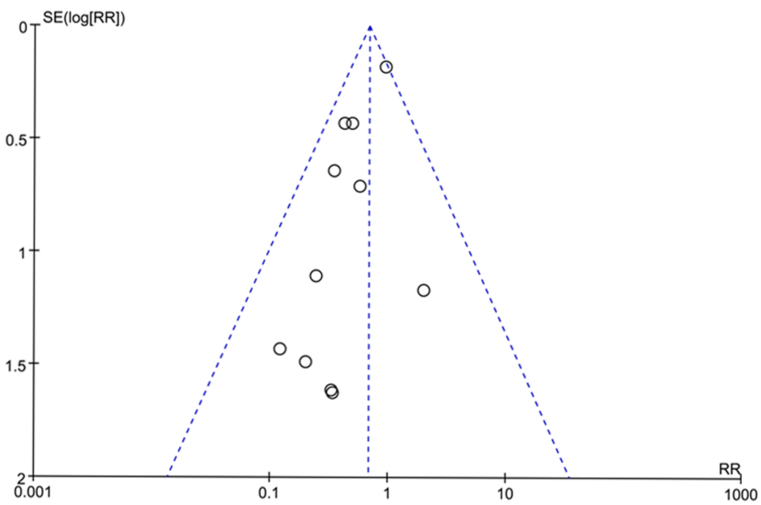

Figure 3. Funnel plot of postoperative pulmonary infection.

2,469 patients in the RFR group and 2,476 patients in the SFR group. The selective procedure is presented in **Figure 1**. Features summarized from qualified RCTs are shown in **Table 1**. We used Cochrane Collaboration's tool to conduct quality assessment and the outcomes are shown in **Figure 2**, which contain risk of bias graph and risk of bias summary.

Publication bias evaluation

When more than ten studies were included in one outcome, we evaluated the publication bias by drawing a funnel plot. Four postoperative outcomes were evaluated; pulmonary, renal dysfunction, anastomotic leakage and length of hospital stay, and the funnel plots are shown in **Figures 3-6**.

Meta-analysis

Postoperative pulmonary infection: We found that postoperative pulmonary infection was reported in 11 studies [5, 7, 8, 18, 21-27] involving a total of 4,059 patients. Heterogeneity tests showed homogeneity ($P = 0.43$, $I^2 = 1\%$). The fixed effect model was used to combine the statistics which showed that the incidence of pulmonary infection was lower in the RFR group (RR: 0.68, 95% CI: 0.52~0.90, $P = 0.007$) (**Figure 7**).

Postoperative psychosis disorders: Seven studies [7, 8, 18-21, 23] reported postoperative psychosis disorders. Heterogeneity tests showed homogeneity ($P = 0.87$, $I^2 = 0\%$). The fixed effect model was used to combine the statistics which showed that the incidence of psychosis disorders was also lower in the RFR group (RR: 0.53, 95% CI: 0.29~0.97, $P = 0.04$) (**Figure 8**).

Postoperative renal dysfunction: A total of 12 studies [5, 7, 8, 16, 18-21, 23-26] including 3,960 patients have reported the complication of renal dysfunction. Heterogeneity test showed homogeneity ($P = 0.12$, $I^2 = 36\%$). The fixed effect model was used to combine the statistics which showed that the incidence of renal dysfunction was higher in the RFR group (RR: 1.49, 95% CI: 1.16~1.90, $P = 0.02$) (**Figure 9**).

Anastomotic leakage: Anastomotic leakage is a kind of operative-related complication. There were 10 studies [5, 7, 8, 17, 19, 21, 22, 24-26] that reported anastomotic leakage. The hetero-

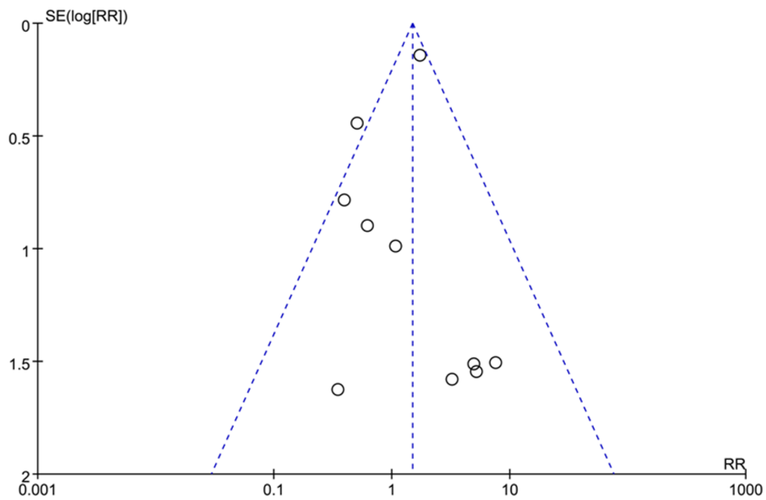

Figure 4. Funnel plot of postoperative renal dysfunction.

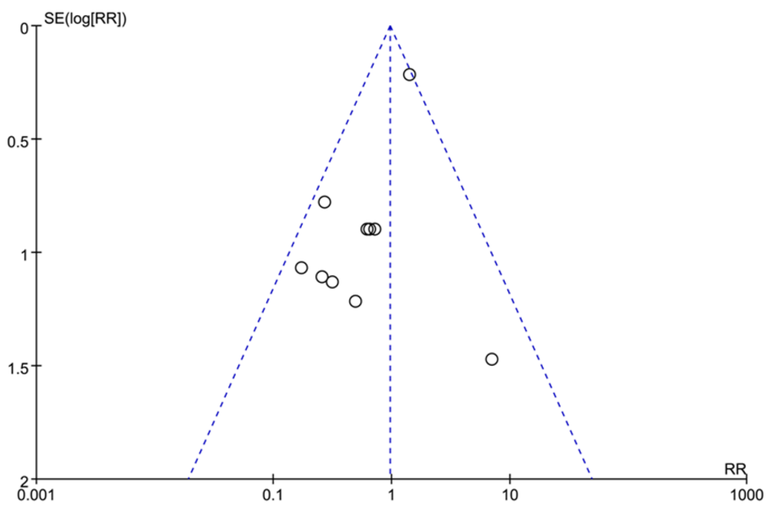

Figure 5. Funnel plot of postoperative anastomotic leakage.

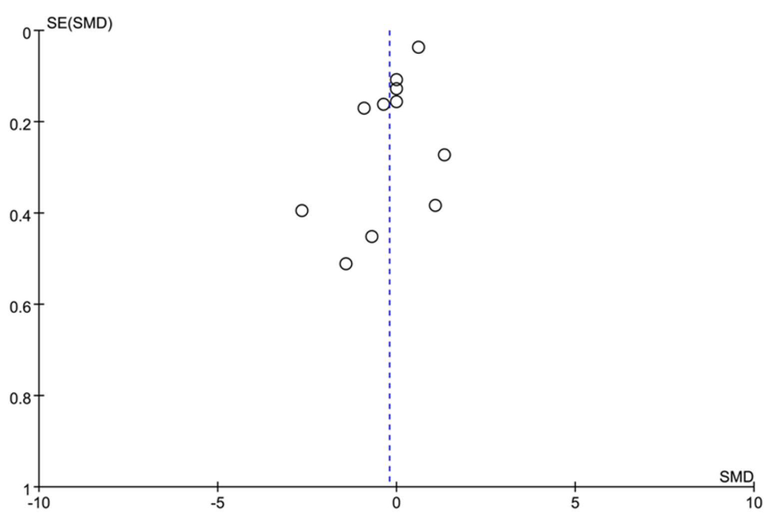

Figure 6. Funnel plot of length of hospital stay.

geneity test of anastomotic leakage showed homogeneity (P = 0.15, I^2 = 32%) and the fixed effect model was used to combine the statistics. The result was (RR: 0.96, 95% CI: 0.69~1.35, P = 0.83) (**Figure 10**), which meant that the incidence of anastomotic leakage had no statistical difference between groups.

Length of hopital stay: Eleven studies [5, 6, 8, 16, 17, 20, 22-25, 27] counted the length of hospital stay. Heterogeneity tests showed heterogeneity in those studies (P < 0.00001, I^2 = 96%). So, the random effect model was used to combine the statistics and the result indicated that there was no statistical difference between groups (SMD: -0.21, 95% CI: -0.64~0.22, P = 0.34). Because of the heterogeneity, we used subgroup analysis. We divided these studies into two groups by region, the European group and the rest of the areas group. A subgroup analysis of the European group [8, 17, 20, 22-24, 27] was carried out by using the random effect model (heterogeneity test P < 0.00001, I^2 = 91%) and the results showed no statistical difference (SMD: -0.05, 95% CI: -0.62~0.53, P = 0.88). Studies [5, 6, 16, 25] from other areas (heterogeneity test P < 0.00001, I^2 = 97%) showed no statistical difference (SMD: -0.48, 95% CI: -1.22~0.25, P = 0.2) (**Figure 11**).

Discussion

The incidence of PPCs after major abdominal surgery is 5.8% [28]. This is harmful and even a small amount of PPC can significantly increase early mortality, as well as the probability of ICU treatment

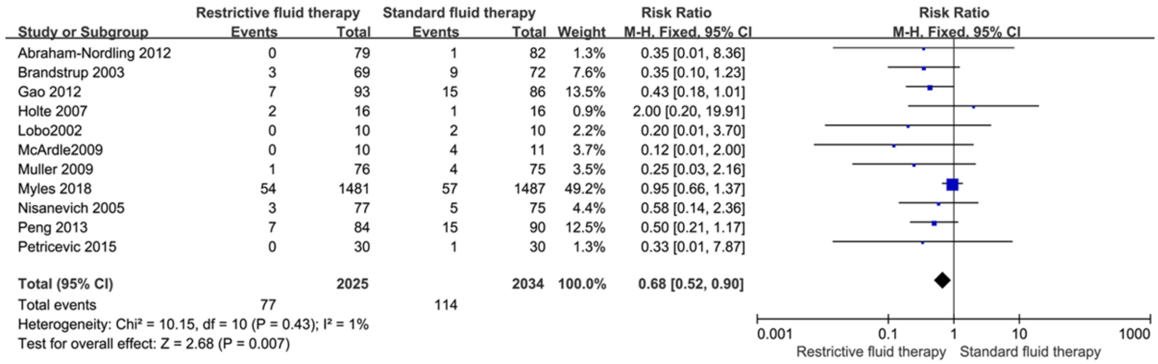

Figure 7. Forest plot of postoperative pulmonary infection.

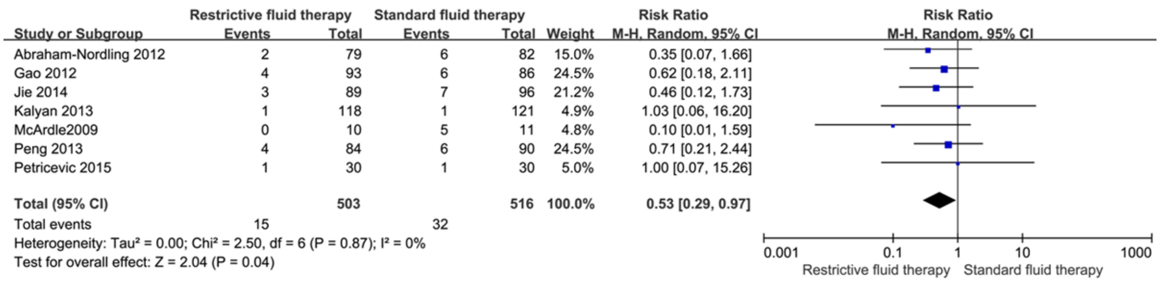

Figure 8. Forest plot of postoperative psychosis disorder.

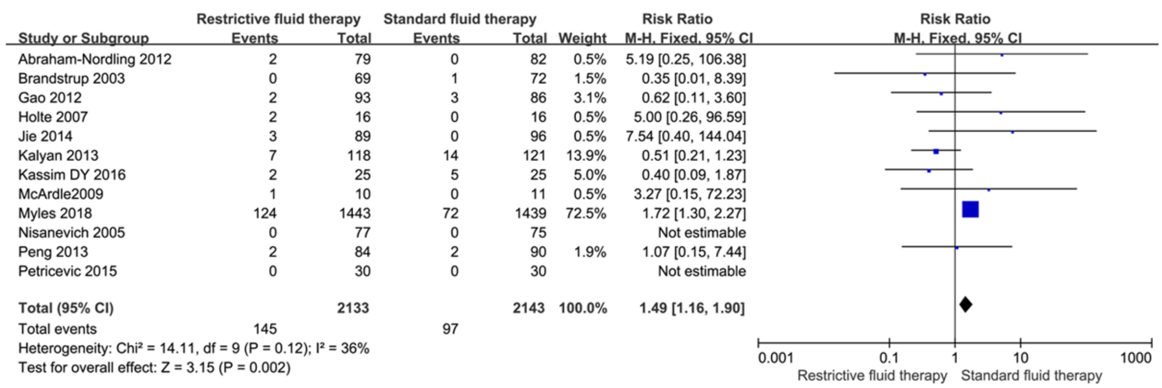

Figure 9. Forest plot of postoperative renal dysfunction.

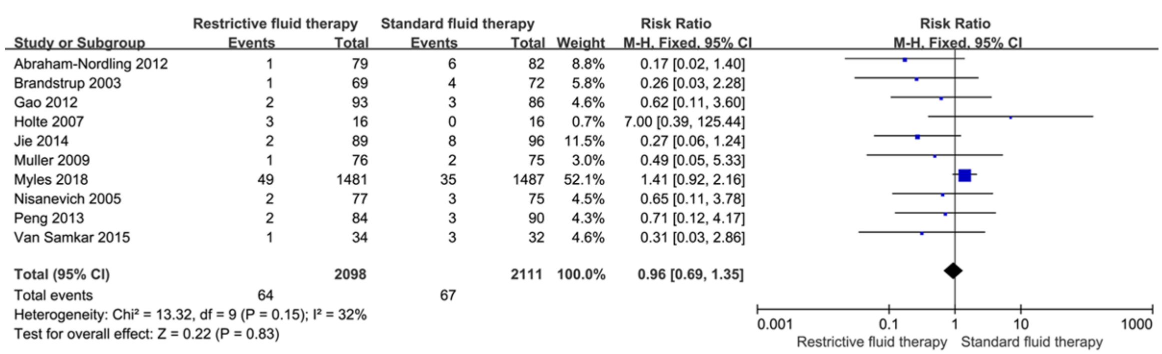

Figure 10. Forest plot of anastomotic leakage.

Study or Subgroup	Restricted fluid therapy Mean	SD	Total	Standard fluid therapy Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
2.2.1 European countries								
Abraham-Nordling 2012	6	0.667	79	6	0.8	82	10.0%	0.00 [-0.31, 0.31]
Holte 2007	10.5	8	16	4	1.75	16	8.0%	1.09 [0.34, 1.84]
Kalyan 2013	8	0.833	118	8	0.833	121	10.2%	0.00 [-0.25, 0.25]
Lobo2002	6	0.33	10	10.025	3.871	10	6.7%	-1.40 [-2.41, -0.40]
McArdle2009	7.78	2.02	10	16	15.99	11	7.3%	-0.68 [-1.56, 0.21]
Muller 2009	5	4.667	76	9	4	75	9.9%	-0.92 [-1.25, -0.58]
Van Samkar 2015	12	0.75	34	10	2	32	9.1%	1.32 [0.79, 1.86]
Subtotal (95% CI)			**343**			**347**	**61.3%**	**-0.05 [-0.62, 0.53]**
Heterogeneity: $Tau^2 = 0.51$; $Chi^2 = 68.62$, df = 6 ($P < 0.00001$); $I^2 = 91\%$								
Test for overall effect: Z = 0.16 (P = 0.88)								
2.2.2 The rest area								
Grant 2016	7	5.167	166	7	9	164	10.3%	0.00 [-0.22, 0.22]
Kassim DY 2016	6.56	0.92	25	9.9	1.5	25	7.9%	-2.64 [-3.42, -1.87]
Myles 2018	6.4	1.167	1490	5.7	1.15	1493	10.5%	0.60 [0.53, 0.68]
Nisanevich 2005	8	2.5	77	9	2.833	75	10.0%	-0.37 [-0.69, -0.05]
Subtotal (95% CI)			**1758**			**1757**	**38.7%**	**-0.48 [-1.22, 0.25]**
Heterogeneity: $Tau^2 = 0.52$; $Chi^2 = 119.69$, df = 3 ($P < 0.00001$); $I^2 = 97\%$								
Test for overall effect: Z = 1.29 (P = 0.20)								
Total (95% CI)			**2101**			**2104**	**100.0%**	**-0.21 [-0.64, 0.22]**
Heterogeneity: $Tau^2 = 0.46$; $Chi^2 = 232.12$, df = 10 ($P < 0.00001$); $I^2 = 96\%$								
Test for overall effect: Z = 0.95 (P = 0.34)								
Test for subgroup differences: $Chi^2 = 0.84$, df = 1 (P = 0.36), $I^2 = 0\%$								

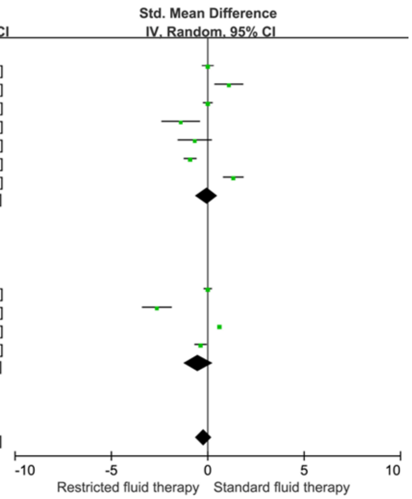

Figure 11. Forest plot of length of hospital stay, and subgroup analysis by different regions.

and prolong the ICU or hospital stay [3]. High ASA grade, esophageal surgery, aged more than 80 years, long operation times, and dependent functional status are effective predictors of PPCs [28]. These factors are hard for doctors to control and we need better therapeutic methods. PPCs should include all pathological changes in the lung that have negative impact on the clinical progress of the patient after surgery [2]. Due to incomplete consistency in evaluation indicators, pulmonary infection was selected in this study. It was significant that the results obtained in this paper helped resolve the controversy over the results of previous studies [12, 13] on meta-analysis (restrictive fluid therapy reduced PPCs) and Myles [5] (there was no difference between the two treatments). The analysis of homogeneity from these studies indicated that the incidence of postoperative pulmonary infection was lower in the RFR group. Anesthesiologists have a great impact on PPCs because mechanical ventilation during the operation is performed by them, but the improvement of PPCs is limited even with protective ventilation [29]. Nevertheless, RFR provides another new solution as a therapeutic method.

Similarly, RFR could reduce postoperative psychosis disorders (RR: 0.53, P = 0.04), which was the expectation of patients and doctors. Indeed, postoperative cognitive dysfunction is the main form of postoperative psychosis disorder, and it is more common in elderly patients. The vast majority of patients undergoing major abdominal surgery are elderly [30]. Therefore, although the mechanism is not fully clear, it does not prevent us from carrying out evidence based clinical treatment.

However, RFR increased the risk of postoperative renal dysfunction (RR: 1.49, P = 0.02). The kidney has large blood flow volumes with the physiological function of regulating systemic liquid volumes and is sensitive to insufficient perfusion. The primary purpose of fluid therapy is to maintain adequately perfusion and oxygenation. From this point of view, RFR resulted in renal dysfunction due to inadequate perfusion. The volume of RFR on the operation day was less than 3,200 ml. Because of the unclear restriction, the idea of restriction may be correct, but there is still room for progress in treatment. Nevertheless, SFR cannot completely eliminate postoperative renal dysfunction. Unfortunately, due to current limitations of equipment and professional, patients do not always receive goal-directed fluid regimens as easily as a restrictive or standard fluid regimen.

Excessive fluid causes intestinal edema, and lack of fluid leads to anastomotic ischemia, all of which may lead to anastomotic leakage. This result showed that SFR and RFR had no significant effect on anastomotic leakage, which means that the total volume range is meaningless for anastomotic leakage.

There was heterogeneity in the analysis of the length of hopital stay, which cannot be well solved by this subgroup analysis. Inconsistent medical processes in different countries and regions may result in differences in duration of stay recording. However, both this and Myles'study [5] believed that these two fluid regimens had no effect on the length of hopital stay.

This study still has some limitations. First of all, although we have searched carefully, we cannot guarantee there are no missing studies. Second, the inclusion and exclusion criteria and follow-up time in each study were not completely consistent, which may lead to a certain degree of inconsistency. Third, because the evaluation indicators and data types were not completely consistent, this results in a reduction in the number of indicators that can be merged.

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Disclosure of conflict of interest

None.

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