



Use of steroids for abdominal tuberculosis: a systematic review and meta-analysis

Hariom Soni¹ · Balaji L. Bellam² · Raghavendra K. Rao³ · Praveen M. Kumar¹ · Harshal S. Mandavdhare² · Harjeet Singh⁴ · Usha Dutta² · Vishal Sharma²

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Abstract

Background The role of adjunctive steroids in abdominal tuberculosis is unclear.

Objective To evaluate effect of adjunctive use of steroids for abdominal tuberculosis in reducing/preventing complications.

Methods We searched electronic databases (Medline, Embase, CENTRAL, Scopus, Web of Science, CINAHL) from inception to 25th June 2018 using the terms “abdominal tuberculosis” OR “intestinal tuberculosis” OR “peritoneal tuberculosis” OR “tuberculous peritonitis” AND steroids OR methylprednisolone OR prednisolone. Bibliography of potential articles was also searched. We included studies comparing adjunctive steroids to antitubercular therapy (ATT) alone. We excluded non-English articles, case reports, reviews and unrelated papers. The primary outcome was a comprehensive clinical outcome including need for surgery or the presence of symptomatic stricture (abdominal pain or intestinal obstruction). Quality assessment of included studies was done using ROBINS-I tool. Random-effects model was used to calculate the summary effect for all the outcomes.

Results Of total 633 records, three studies on peritoneal tuberculosis were included in meta-analysis. These papers were of poor quality (one quasi-randomised study and two retrospective cohort studies). Meta-analyses showed adjunctive steroids, with ATT is more effective than ATT alone in tuberculous peritonitis patients for the prevention of composite end point (RR 0.15 [0.04, 0.62], $p=0.008$), symptomatic stricture (RR 0.15 [0.04–0.62] $p=0.008$) and intestinal obstruction (RR 0.18 [0.03–0.99] $p=0.05$).

Conclusion The data on use of steroids for abdominal tuberculosis are limited to peritoneal tuberculosis. Although steroids seem to have some benefit in patients of tubercular peritonitis, the poor quality of studies limits the generalisability of the findings.

Systematic review registration number CRD42016047347.

Keywords Abdominal tuberculosis · Tuberculous peritonitis · Antitubercular therapy · Steroids · Stricture · Surgery

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✉ Vishal Sharma
docvishalsharma@gmail.com

¹ Department of Pharmacology, Post Graduate Institute of Medical Education and Research (PGIMER), Chandigarh, India

² Department of Gastroenterology, Post Graduate Institute of Medical Education and Research (PGIMER), Chandigarh, India

Introduction

Abdominal tuberculosis is a common form of extrapulmonary tuberculosis. It can present with diverse clinical scenarios and can involve the gastrointestinal tract, lymph nodes,

³ Department of Cardiology, Post Graduate Institute of Medical Education and Research (PGIMER), Chandigarh, India

⁴ Department of General Surgery, Post Graduate Institute of Medical Education and Research (PGIMER), Chandigarh, India

peritoneum or visceral organs (liver, spleen, pancreas, etc.) alone or in any combination of these [1]. Abdominal tuberculosis (TB) may involve any part of the gastrointestinal (GI) tract and accounts for around 11% of all cases of extrapulmonary tuberculosis [2]. GI involvement by TB disease can occur either in primary or post-primary disease: (1) by swallowing of infected sputum in pulmonary tuberculosis (PTB) patients, (2) by ingestion of contaminated food (especially unpasteurized milk or dairy products), (3) by lymphatic or (4) haematogenous spread and, rarely, (5) by spread from adjacent organs (e.g. fallopian tubes). Thus, the disease can affect any part of the digestive tract from the oesophagus to the rectum, but the characteristic site of involvement is the ileocecal area, an area rich in lymphoid tissue and the region where physiologic stasis of the bowel content occurs [3, 4].

Peritoneal involvement is not an uncommon presentation of tuberculosis (TB). Tuberculous peritonitis (TBP) could be demonstrated in around in 0.1–3.5% of all patients with pulmonary disease and has been reported to constitute around 4–10% of all extrapulmonary TB [5]. Peritoneal tuberculosis could present with abdominal discomfort or distension, abdominal pain, features of intestinal obstruction (due to adhesions) and constitutional features such as pyrexia, weight loss, abdominal tenderness and ascites [6].

The treatment of TBP is primarily conservative. Anti-TB regimens identical to those for pulmonary TB are employed for therapeutics [7]. The surgical intervention is reserved for complications arising from adhesions and inflammation, which includes bowel perforation, intestinal obstruction, fistulae, abscesses, and haemorrhage [8].

The benefit of steroid administration in addition to ATT has been noted for few conditions, notably pericarditis and meningitis [7]. To date, it is unclear if adjunctive use of steroids could be of benefit in patients with abdominal tuberculosis. The argument in favour of its use could be related to possible reduction in tubercular fibrotic strictures or improvement in strictures present at initial therapy. This could result in a reduction in patients with symptoms such as abdominal pain, intestinal obstruction and need for surgery. Possible risks with use of steroids could be flaring of the disease (especially multidrug resistant tuberculosis), adverse effects of steroids. Further some of the patients treated as intestinal tuberculosis with ATT and steroids could actually have underlying Crohn's disease and the use of steroids may mask the recognition of underlying Crohn's disease [9, 10]. With this background, we tried to evaluate the role of adjuvant steroids in abdominal tuberculosis by conducting a meta-analysis of the existing literature available.

The objective of this systematic review and meta-analysis is to systematically collect, critically appraise, and synthesise available evidence regarding the use of corticosteroids as adjuvant to antitubercular therapy in patients with abdominal tuberculosis for the prevention of complications. The

studies which compared the use of ATT alone with ATT and steroids in abdominal tuberculosis were included irrespective of the study design. The primary outcome for the systematic review was a combined clinical parameter including symptomatic stricture, episodes of intestinal obstruction or need for surgery.

Methods

Study design

We conducted a systematic review with meta-analysis with a frequentist approach using a pre-specified study protocol which was registered on PROSPERO in Nov 2016 (CRD42016047347). The study was reported according to the PRISMA statement for systematic review and meta-analysis [11].

Search strategy and selection criteria

Independently, two authors (HS and BLB) trained in pharmacology and clinical gastroenterology, respectively, searched several databases including Medline, Embase, CENTRAL, Scopus, CINAHL and Web of science for relevant studies on the abdominal TB from inception to June 25th 2018. The search terms used were abdominal tuberculosis, intestinal tuberculosis, peritoneal tuberculosis, tuberculous peritonitis, tubercular peritonitis, steroid, methylprednisolone, prednisolone and prednisone (Detailed search strategy in Supplementary Table 1). We had also searched Clinical trial registries (<https://www.clinicaltrial.gov>) for registered trials. These terms were searched in the abstracts, keywords and titles field. The inclusion was restricted to clinical studies that were published in English. We also searched the bibliography of the selected articles to retrieve other related studies.

Study selection

HS and BLB independently assessed the titles and abstracts from studies for inclusion in the search results. All studies reporting data on adjunctive steroid with antitubercular therapy used in abdominal tuberculosis/tuberculous peritonitis were selected for meta-analysis. Any study which was deemed as eligible by even a single reviewer underwent a full text screening. Disagreements were resolved by discussion between three authors (HS, BLS and VS). We included children or adults of either sex with confirmed diagnosis of abdominal tuberculosis/peritoneal tuberculosis and ATT with steroids in any of the group in the study. We excluded the articles published in languages other than English language, case reports, reviews and unrelated studies.

Outcomes

We used ‘comprehensive clinical outcomes’ including need for surgery and symptomatic stricture (abdominal pain, intestinal obstruction) as the primary outcome of data analysis and this includes. The secondary outcomes analysed were prevention of intestinal obstruction, decrease in the need for surgical intervention, and mortality benefit and any adverse effects with steroid use along with ATT.

Data extraction

Two reviewers (HS, BLB) independently extracted data from the selected studies. Data were extracted using a predefined template that included the following information: study type, year of publication, study setting (country), target population (gender and age), intervention type, short-term and long-term complication of abdominal tuberculosis and analysis perspective.

Quality assessment

Assessment of risk of bias of included studies was done by two investigators (HS and VS) individually, used the Cochrane’s tool for assessing the risk of bias for non-randomised studies of interventions (ROBINS-I) [12]. This tool is used for assessment of bias in non-randomised studies such as the case–control, cohort or quasi-randomised trials. It includes assessment of the studies across three major domains (pre-intervention, at the time of intervention and after the intervention). Pre-intervention parameters which were assessed included any bias due to confounding or arising out of the selection of patients. For the intervention related domain any bias originating from the classification of interventions was assessed. Finally, post-intervention domain assessment was done by assessing any deviations from the proposed intervention, missing information, bias in outcome assessment and biased or selective outcome reporting. The possible judgements were divided into five levels, namely “low risk”, “moderate risk”, “serious risk”, “critical risk” and “no information” level based on the grading recommendations of ROBINS-I scale.

Data analyses/statistical analysis

All the outcomes of interest (i.e. comprehensive clinical outcomes, intestinal obstruction, need for surgical intervention and mortality benefit) were dichotomous. All the outcomes were represented as risk ratio (RR) as it provides a more intuitive clinical interpretation of outcomes as against employment of odds ratio and risk difference.

Random-effects model was used to calculate summary effect of the study for all the outcomes. Random-effects

model was chosen for determining summary effect, as the included studies varied in their study design, and patient population employed were heterogeneous. Heterogeneity between the studies was assessed using I^2 statistic and Cochrane Q test.

We did not formally assess for the presence of any publication bias as the number of included studies were small. We used the Review Manager 5.3 (Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014) for all statistical analyses.

Results

Study search and study selection

Systematic searching from inception to June 25, 2018, yielded 633 records (Fig. 1). After removal of duplicates, 417 potential records were further screened for title and abstract. After reading title and abstract, 411 article were removed (176 case record, 51 duplicates, 58 review, 43 unrelated studies, 27 articles were present in other language, 14 retrospective study, 12 letter to editor, 7 invitro studies, 6 animal study, 6 case series, 3 systematic review, 2 editorials and 6 were others including book, comments, proceedings, recommendations, survey and user guide). The full texts of the remaining six articles were read by two investigators and three were found eligible for meta-analysis [13–15]. The reasons for exclusion of the other three studies [16–18] are explained in Table 1.

Characteristics of selected studies

All the three included studies had evaluated the role of steroids as adjuvant to ATT in prevention of complications in tuberculous peritonitis patients (Table 2). No studies reporting outcomes in the other form of abdominal tuberculosis, i.e. intestinal tuberculosis were found. The total number of participants was 108 of tuberculous peritonitis out of which 50 participants had received steroids along with ATT and 58 patients received only ATT. Singh M used oral prednisolone 30 mg for three months along with ATT in intervention group of 23 patients subsequently one month used for tapering the steroid [13]. Similarly, Demir and Alrajhi used 20 mg methyl prednisolone in 18 patients for 15 days and 0.5–1 mg/kg/day prednisolone for mean duration of 6.6 month (4–9 months range) in nine patents of tuberculous peritonitis, respectively [14, 15]. The steroid tapering rate were 5 mg/5 days in Demir and 5–10 mg/10–15 days in Alrajhi, respectively [14]. (Table 2).

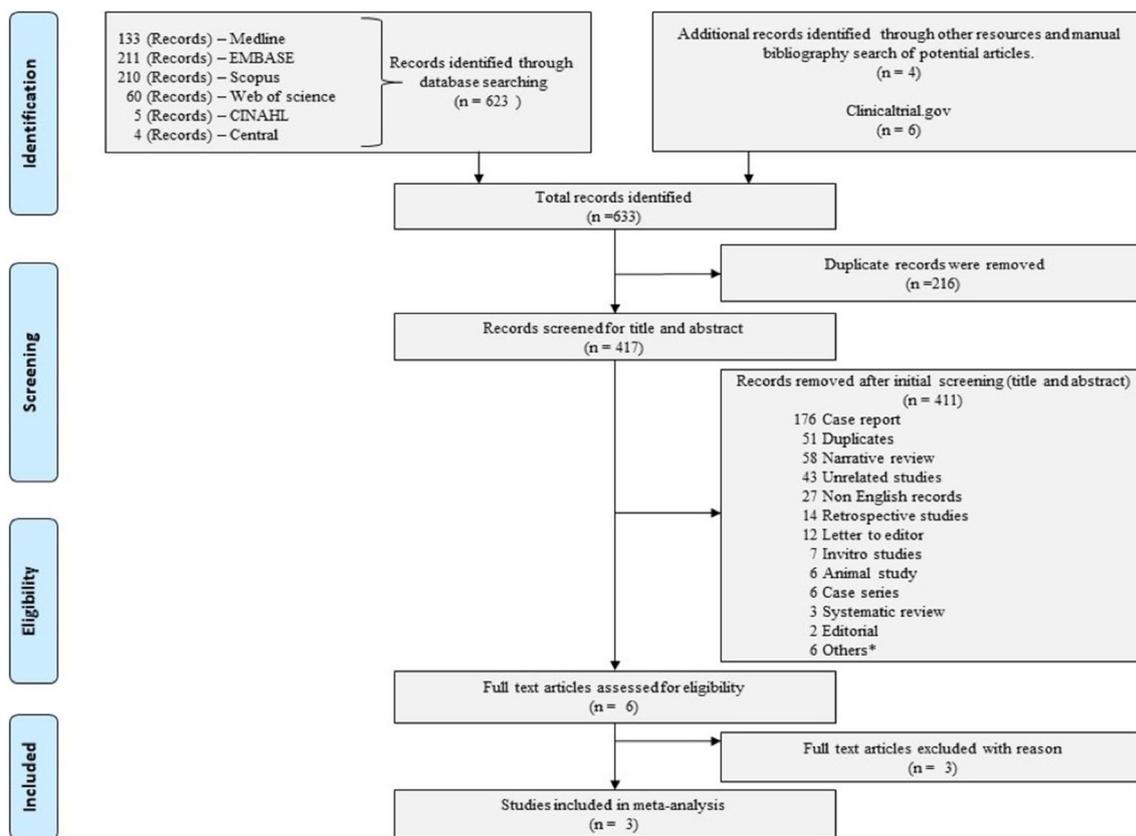


Fig. 1 Flow chart of the literature search (PRISMA flow chart)

Table 1 Description of excluded studies after full text reading

No	Study	Study design	Reason for exclusion
1.	Bastani 1985	Case-control	Outcome data not separately provided, prednisone was given to more than half patients of tubercular peritonitis but no data on outcomes was reported
2.	Poyrazoglu 2008	Observational study	Clinical review of 23 patients with tuberculous peritonitis but no data of use of adjuvant steroids in treatment
3.	Veeragandham 1996	Retrospective study	No data of use of steroids in abdominal TB patients

Quality assessment

The out of three included studies, one was quasi-randomised trial (Singh M 1969), one was case-control study (Alrajhi 1998) and one was cohort study (Demir 2001) [13–15]. The Singh was quasi-randomised study which had lack of information in confounding factors and deviations from intended interventions with low risk of bias in all other domains. Overall risk of bias falls in no information category [13]. Alrajhi had overall moderate risk of bias due to moderate bias in selection of participants and there was lack of information in deviation of intended intervention [14]. Demir had overall serious risk of bias due to serious bias in selection of participants and classification of interventions [15].

(Table 3). The data extracted from the three included studies are shown in Supplementary Table 2.

Efficacy of steroids

Meta-analysis of included three studies showed that adjuvant steroids were more effective than ATT alone in prevention of comprehensive clinical outcome in patients with tuberculous peritonitis. All three studies reported the complication proportions in both the groups (case and control) and the pooled risk ratio (RR) of symptomatic stricture (abdominal pain and/or intestinal obstruction) was 0.15 (95% CI 0.04–0.62, $p=0.008$) (Fig. 2). Though the I^2 value is below 50%, Cochran's Q p value turned non-significant ($p=1.00$)

Table 2 Characteristics of included studies

Study	Region	Study population	Study design	Sample size (n)	Gender	Follow-up duration Mean (range)	Randomization	ATT		Steroid			
								Intensive phase (daily dose)	Continuation phase (daily dose)	Drug	Dose	Duration	Tapering
Singh 1969	India	Tubercular peritonitis	RCT	ATT + steroid = 23 ATT alone = 24 Total = 47	M = 20 F = 27	3.1 (2–5.8) years	Quasi	H = 300 mg, 3 month S = 1 gm, 3 month	H = 300 mg, 15 month PAS = 12 gm, 15 month Ethio = 500 mg, 15 month	Prednisolone	30 mg	3 months	1 month
Alrajhi 1998	Saudi Arabia	Tubercular peritonitis	Case-control study	ATT + steroid = 9 ATT alone = 26 Total = 35	M = 17 F = 18	24 (2–118) months	Not described	R H (one control received only R)		Prednisone	0.5–1 mg/kg/day	Mean 6.6 month (4–9 month)	5–10 mg/10–15 days
Demir 2001	Istanbul	Tubercular peritonitis	Case-control study	ATT + steroid = 18 ATT alone = 8 Total = 26	M = 11 F = 15	19 (6–36) months	Not described	H = 300 mg, 2 month Z = 2 gm, 2 month S = 1 gm, 2 month	H = 300 mg, 4 month E = 1.5 gm, 4 month	Methyl prednisolone	20 mg	15 days	5 mg/5 days

E Ethambutol, *Ethio* Ethionamide, *H* Isoniazid, *PAS* Para-aminosalicylic acid, *R* Rifampin, *S* Streptomycin, *Z* Pyrazinamide

which further justifies the selection of random effect model for determination of the summary effect.

Similarly, pooled RR for only intestinal obstruction was evaluated and found significant with the use of steroid 0.18 (95% CI 0.03–0.99, $p = 0.05$) (Fig. 3). The pooled RR for need for surgery was 0.21 (95% CI 0.03–1.62, $p = 0.14$) which did not approach to the significant level (Fig. 4).

Mortality was seen in the three cases of ATT alone group in Alrajhi study and absent in any group in Singh study so this outcome was not included in meta-analysis. In the study by Alrajhi et al., three controls died. The cause of mortality was related to the complications of intestinal obstruction, hepatic cirrhosis and gastrointestinal bleeding related to hepatitis C virus infection and multi-organ failure in one

Table 3 Assessment of bias for each study, using the ‘the risk of bias in non-randomised studies—of interventions (ROBINS-I)’ assessment tool: included studies

Study	Bias due to confounding	Bias in selection of participants into the study	Bias in classification of intervention	Deviation of intended intervention		Bias due to missing data	Bias in measurement of outcomes	Bias in selection of the reported result	Overall bias
				Effect of assignment of intervention	Effect of starting and adhering to intervention				
Alrajhi 1998	No information	Low	Low	Moderate	Moderate	Low	Low	Low	Moderate
Demir 2001	No information	Serious risk	Serious risk	Low	Low	Low	Low	No information	Serious
Singh 1969	No information	Low	Low	No information	No information	Low	Low	Low	No information

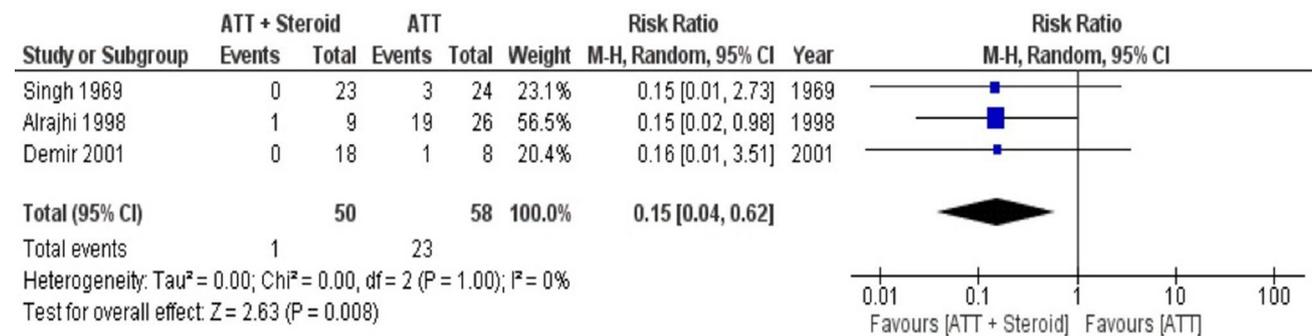


Fig. 2 Forest plot comparing the two groups for the primary objective—symptomatic stricture (abdominal pain and/or intestinal obstruction/surgery)

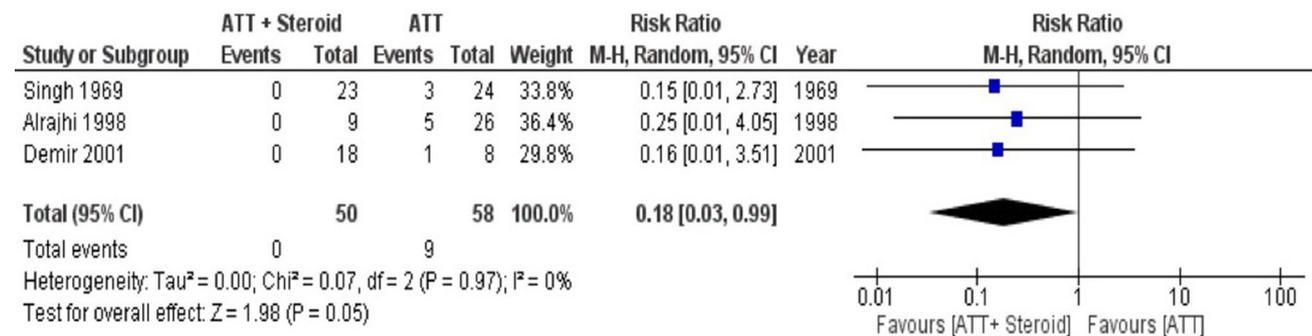


Fig. 3 Forest plot comparing the two groups for the occurrence of intestinal obstruction

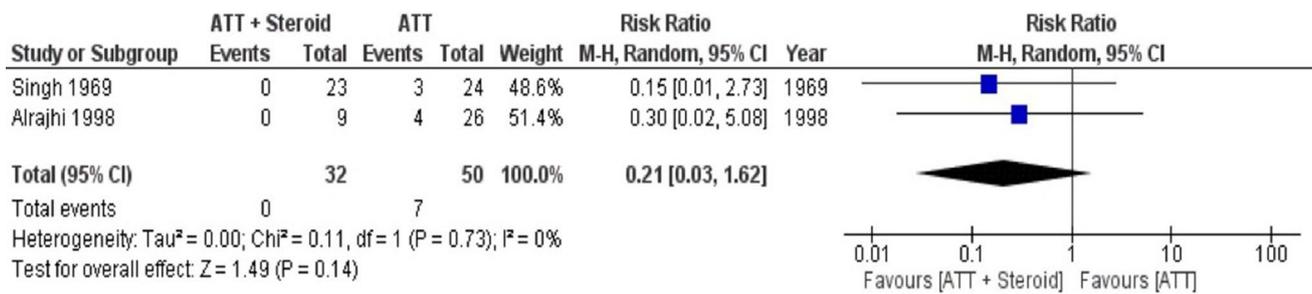


Fig. 4 Forest plot comparing the two groups for the need for surgery

and debilitation, massive ascites, and sepsis in one patient each. No case receiving steroids died.

Safety of steroids

Only the study by Alrajhi reported adverse drug reactions in three patients out of 24 in ATT with steroid group so this outcome was not included in meta-analysis [14]. The reported side effects were epigastric pain in two cases which was treated with ranitidine and antacids. In another case, an increased requirement of the oral hypoglycemic requirements was reported. These side effects abated once the course of steroids had been completed.

Discussion

Abdominal tuberculosis is characterised by variable patterns and severity of involvement. Although the term is used for any of the four patterns (luminal, peritoneal, visceral and abdominal lymph nodal) or a combination of any of them, the common patterns are peritoneal and intestinal involvement. Strictures could occur in intestinal tuberculosis and it is well recognised that only a subset of strictures present at the time of presentation respond to antitubercular therapy. A recent report suggested that only half of the patients with symptomatic tubercular intestinal strictures are relieved of their symptoms with antitubercular therapy [19]. The resolution of strictures (as documented on endoscopy or radiology) is still less frequent and occurs in around a quarter of the patients. Similar findings have also been reported from other studies. A substantial proportion of these patients eventually requires surgical intervention or endoscopic dilatation [8, 19]. Tubercular strictures are believed to have two components: inflammatory and fibrotic. It is believed that ATT may help in alleviation of the inflammatory component but healing is associated with fibrosis and may result in fibrotic intestinal strictures. Further, patients with peritoneal tuberculosis also could have abdominal pain and features of intestinal obstruction

related to the occurrence of peritoneal adhesions and fibrosis or formation of abdominal cocoon [6, 20]. Therefore, there is an unmet need for therapies which could help in improvement of tubercular intestinal strictures and help in their resolution.

Steroids are a candidate for such therapies as they have been demonstrated to be of benefit in conditions such as tubercular meningitis and pericarditis. They have demonstrated mortality benefit in tubercular meningitis [21]. In tubercular pericarditis, it is believed that the reduction in inflammation may reduce rates of constrictive pericarditis and may therefore result in reduction in long-term sequelae. Indeed the recent Indian extrapulmonary tuberculosis guidelines, on basis of a systematic review of six studies, suggested that steroid use helps in reduction of tubercular pericarditis related mortality and possibly rates of constrictive pericarditis and recommended its use [7]. Similar to these conditions, it is possible that the use of steroids in intestinal and peritoneal tuberculosis could result in reduction of fibrotic consequences and reduce the rates of stricture formation and post tubercular sequelae. None of the published guidelines have addressed the issue of use of steroids in abdominal tuberculosis.

We, therefore, conducted a systematic review and a meta-analysis of the studies reporting the use of steroids in abdominal tuberculosis. The literature on use of steroids in peritoneal tuberculosis is limited to three studies which included one quasi-randomised study. The studies cannot be generalised to the current practice because of notable differences between the studies and current therapeutic strategies. None of these reports have used the current antitubercular therapy, i.e. 2 months of four drugs (HRZE) followed by 4 months of three drugs (HRE). The study by Singh M et al. reported a very high positivity of AFB in peritoneal fluid (83%) which is unusual as most studies report a very low AFB positivity [13]. These differences could be related to the differences in disease severity or possibly related to the fact that a litre of peritoneal fluid was processed for AFB testing. The other two studies are retrospective in nature and it is unclear how the clinicians made the decision to

prescribe steroids or not [14, 15]. All three studies used different doses and duration of steroids.

In spite of these caveats, all three studies do demonstrate benefit of use of steroids.

The present systematic review demonstrates the lack of literature on use of steroids in abdominal tuberculosis. Our literature search identified multiple lacunae in the state of the research in this area. No studies have reported the use of steroids in the intestinal tuberculosis. This is the condition where the stricturing disease is more likely to be encountered and the steroid therapy is most likely to be beneficial. However, there are multiple challenges to the conduct of such a study. The microbiological and histological positivity in intestinal tuberculosis is low, and therefore, in countries endemic for tuberculosis, clinicians often start empirical ATT for suspected intestinal tuberculosis [1]. Some of these patients have underlying Crohn's disease (CD) and mucosal healing at 2 months or end of ATT is used to differentiate these two conditions [9, 10]. Steroids are the initial therapy of choice for active CD and therefore would help in improvement of CD. Therefore, such trials in intestinal TB should preferably exclude CD which is difficult to achieve in real life situations.

In conclusion, the limited literature on use of steroids in peritoneal tuberculosis suggests that symptomatic sequelae of tuberculosis could be prevented by use of steroids. However, the available literature is limited by the quality of the studies and the fact that literature is available only in peritoneal tuberculosis.

Author contributions VS, HaS (Harjeet Singh): Conception. HS (Harion Soni), BLB, VS: Literature search. HS, BLB, RRK, PMK, VS: Data extraction and risk of bias assessment. HS, BLB, RRK, PMK, VS: Data analysis. HS, BLB, VS: Initial draft. HSM, HaS, UD, VS: Important intellectual content and manuscript revision. HS, BLB: Equal contribution. All authors: final approval.

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Compliance with ethical standards

Conflict of interest None.

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