臺北市立萬芳醫院 - 委託財團法人臺北醫學大學辦理
Taipei Municipal Wan fang Hospital (Managed by Taipei Medical University)

使用Metronidazole
是否可以改善痔瘡術後疼痛問題

引言人：王廷光

日期：2019/11/26 12:00~13:00

REVIEW ARTICLE

ANZJSurg.com

Metronidazole following excisional haemorrhoidectomy: a systematic review and meta-analysis

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Key words
colorectal surgery, general surgery, haemorrhoid, haemorrhoidectomy.

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Accepted for publication 5 August 2017.

doi: 10.1111/ans.14236

Abstract

Background: Post-operative pain is a major issue following excisional haemorrhoidectomy. Although metronidazole by both oral and topical administration routes has been shown to reduce pain after haemorrhoidectomy, its use remains a contentious issue. This systematic review and meta-analysis aims to investigate the effect of metronidazole on post-operative pain after excisional haemorrhoidectomy.

Methods: A systematic review of the literature was conducted according to Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines. Randomized controlled trials (RCTs) published in PubMed/MEDLINE, EMBASE, CENTRAL and CINAHL, from inception to December 2016 were retrieved. The primary outcome investigated was post-operative pain reported as visual analogue score (VAS). Secondary outcomes were analgesia use, complications and time to return to normal activity. Meta-analysis was performed using Review Manager version 5.3 software.

Results: Nine randomized controlled trials including 523 patients were included in the final analysis. Five studies used oral administration and four used topical. Meta-analysis showed that post-operative VAS of patients receiving metronidazole by either route was significantly less than those in comparison groups. VAS means decreased at all the time points for both oral and topical metronidazole. Topical and oral routes of administration were not compared in any study. There was no increase in complication rates and return to normal activity was significantly earlier for patients receiving metronidazole (−4.49 days; 95% confidence interval [−7.70, −1.28]; $P = 0.006$).

Conclusions: Both topical and oral metronidazole reduce post-operative pain without an increase in complication rates and result in an earlier return to normal activity. Further work is required to determine which the optimum route of administration is.

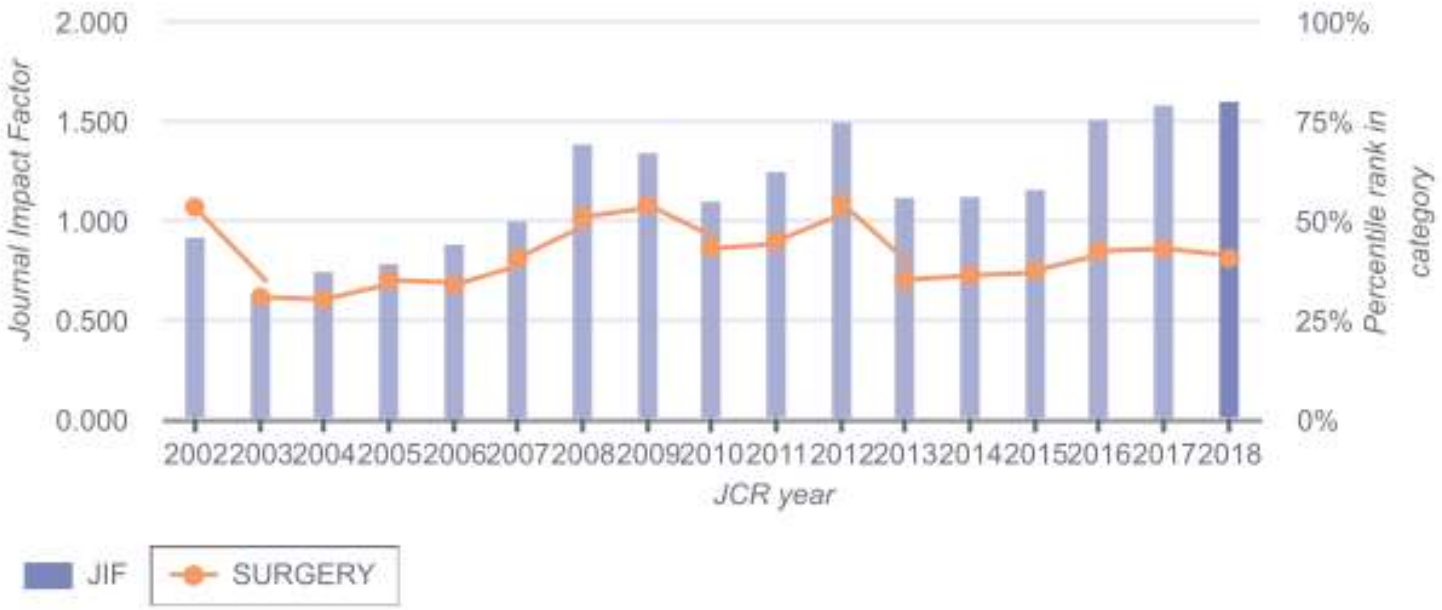
InCites Journal Citation Reports

Clarivate Analytics

2018 Journal Impact Factor & percentile rank in category for: ANZ JOURNAL OF SURGERY

1.605

2018 Journal Impact Factor



Background

- Aims to investigate the effect of metronidazole on postoperative pain after excisional hemorrhoidectomy.

Volume 88, Issue 5
May 2018
Pages 408-414

Background

THE LANCET
Volume 351, Issue 9097, 17 January 1998, Pages 169-172

Articles

Double-blind randomised controlled trial of effect of metronidazole on pain after day-case haemorrhoidectomy

Emin A Carapeti FRCS[Eng] [a], Michael A Kamm FRCP [a], Peter J McDonald FRCP [a], Robin KS Phillips FRCP [a]

Show more

https://doi.org/10.1016/S0140-6736(97)09003-X

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Colorectal Disease

Systematic Review | Full Access

Systematic review and meta-analysis of the role of metronidazole in post-haemorrhoidectomy pain relief

N. J. R. Lyons, J. B. Cornille, S. Pathak, P. Charters, I. R. Daniels, N. J. Smart

First published: 07 June 2017 | https://doi.org/10.1111/codi.13755 | Citations: 5

Diseases of the Colon & Rectum. 60(4):446–455, APRIL 2017
DOI: 10.1097/DCR.0000000000000792, PMID: 28267013
Issn Print: 0012-3706
Publication Date: April 2017

Print

Systemic Metronidazole May Not Reduce Posthemorrhoidectomy Pain: A Meta-Analysis of Randomized Controlled Trials

Kerollos Wanis;Heather Emmerton-Coughlin;Shaun Coughlin;Norine Foley;Christopher Vinden;

Background

- Bacteria are known to colonize hemorrhoidectomy wounds (DePaula, 1991), and some investigators postulate that this colonization may lead to secondary infection and could be one of the factors responsible for postoperative pain (Carapeti, 1998).

Paravastu, S. C. V., & Slater, R. (2013). Metronidazole for pain after haemorrhoid surgery. *Cochrane Database of Systematic Reviews*, (8).

Background

- Decreasing secondary bacterial colonization or infection, and hence reduction of post-operative inflammation and edema that causes pain.
- Direct anti-inflammatory response.

Xia, W., Manning, J. P., Barazanchi, A. W., Su'a, B., & Hill, A. G. (2018). Metronidazole following excisional haemorrhoidectomy: a systematic review and meta-analysis. *ANZ journal of surgery*, *88*(5), 408-414.

Background

- Defined as the symptomatic enlargement and / or distal displacement of anal cushions, which are prominences of anal mucosa formed by loose connective tissue, smooth muscle, arterial and venous vessels.
- The true prevalence of hemorrhoids is unknown.

Lohsiriwat, V. (2015). Treatment of hemorrhoids: A coloproctologist's view. *World Journal of Gastroenterology: WJG*, *21*(31), 9245.

Background

- One of the most common medical conditions in general population.
- Clinically characterized by painless rectal bleeding during defecation with or without prolapsing anal tissue.
- Type: internal hemorrhoid and external hemorrhoid.

Lohsiriwat, V. (2015). Treatment of hemorrhoids: A coloproctologist's view. *World Journal of Gastroenterology: WJG*, *21*(31), 9245.

Background

Grade 1	Grade 2	Grade 3	Grade 4	Complicated

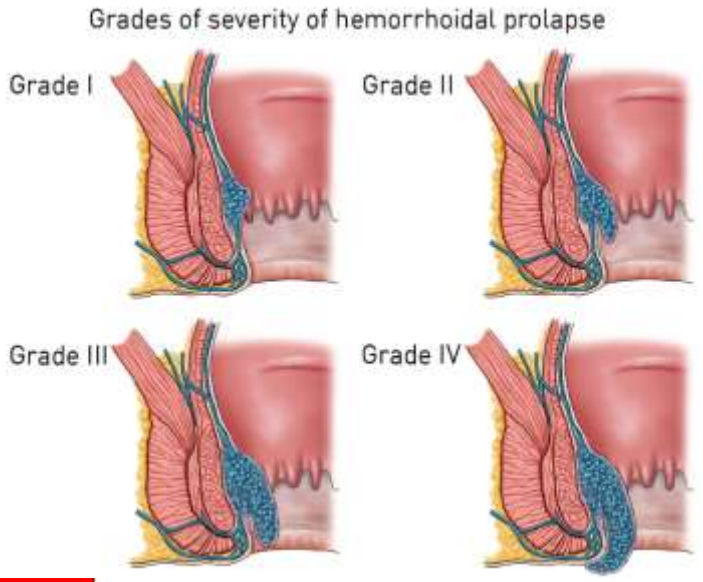
Dietary and lifestyle modification
(such as high-fiber diet, laxatives, hydration, avoidance of straining)

Medication
(topical or systemic)

Office-based procedure
(such as banding, sclerotherapy)

Non-excisional operation
(such as DG-HAL, SH/PPH)

Excisional operation
(such as open and closed hemorrhoidectomy)



From https://images.app.goo.gl/HiQEptoSxduWkkXJ8

Lohsiriwat, V. (2015). Treatment of hemorrhoids: A coloproctologist's view. *World Journal of Gastroenterology: WJG*, *21*(31), 9245.

Background

- The traditional surgical approach:
  - Open (Milligan-Mor-gan) hemorrhoidectomy
  - Closed (Ferguson) hemorrhoidectomy
- Postoperative pain is a significant problem (Shanmugam, 2005; Sneider, 2010)
- Prolonged hospital stay, readmissions and delayed return to daily activities (PROSPECT, 2011).

Paravastu, S. C. V., & Slater, R. (2013). Metronidazole for pain after haemorrhoid surgery. *Cochrane Database of Systematic Reviews*, (8).

Background

- Minimally invasive operations have been introduced into surgical practices in order to avoid post-hemorrhiodectomy pain.

Lohsiriwat, V. (2015). Treatment of hemorrhoids: A coloproctologist's view. *World Journal of Gastroenterology: WJG*, *21*(31), 9245.

Background

- Glyceryl trinitrate cream, Calcium channel blockers, Botox injection (Siddiqui, 2011)
- Bupivacaine (Haas, 2012)
- Sucralfate solution (Ala, 2013)
- Acupuncture (Langenbach, 2012).
- Metronidazole, in the United Kingdom, is widely used.

Paravastu, S. C. V., & Slater, R. (2013). Metronidazole for pain after haemorrhoid surgery. *Cochrane Database of Systematic Reviews*, (8).

Appraisal sheets(FAITH)

- Appraisal Tool
  - [統合分析 Meta-analysis]
    - 步驟1：研究探討的問題為何 (PICO)
    - 步驟2：研究的品質如何 (內在效度)
    - 步驟3：研究結果之意義為何 (效益)

Appraisal FAITH 系統性文獻回顧快速評讀表

➢ 步驟 1：系統性文獻回顧探討的問題為何？

研究族群 / 問題 (Population/ Problem) :

- Excisional Hemorrhoidectomy

介入措施 (Intervention) :

- Metronidazole

比較 (Comparison) :

- Standard cares

結果 (Outcomes) :

- Reduce post-operative pain without increase in complication rates, early return to work and analgesia consumption

Appraisal sheets(FAITH)

- Appraisal Tool
  - [統合分析 Meta-analysis]
    - 步驟1：研究探討的問題為何 (PICO)
    - 步驟2：研究的品質如何 (內在效度)
    - 步驟3：研究結果之意義為何 (效益)

Appraisal FAITH - 步驟 2：系統性文獻回顧的品質如何(F)

【F】研究是否找到 (Find) 所有的相關證據？

良好的文獻**搜尋**至少應包括二個主要的**資料庫**(如：Medline, Cochrane 考科藍實證醫學資料庫, EMBASE等)，並且加上文獻**引用檢索**(參考文獻中相關研究、Web of Science, Scopus或Google Scholar)、試驗登錄資料等。
文獻搜尋應不只限於英文，並且應同時使用 MeSH字串及一般檢索詞彙(text words)。

Literature search

A comprehensive review of the literature was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement.[13] An electronic database search was undertaken involving PubMed/MEDLINE (1946 to present), EMBASE (1980 to present), Cochrane Central Register of Controlled Trials (CENTRAL) (inception to present) and CINAHL Plus (1937 to present). Reference lists from all included trials were manually reviewed to identify any additional studies. Appendix S1 shows the search terms used in PubMed/MEDLINE and adapted for EMBASE and CENTRAL. The search was limited to humans. The last search was run on 1 December 2016.

Appraisal FAITH - 步驟 2：系統性文獻回顧的品質如何(F)

【F】研究是否找到 (Find) 所有的相關證據？

良好的文獻**搜尋**至少應包括二個主要的**資料庫**(如：Medline, Cochrane 考科藍實證醫學資料庫, EMBASE 等)，並且加上文獻**引用檢索**(參考文獻中相關研究、Web of Science, Scopus或 Google Scholar)、試驗登錄資料等。
文獻搜尋應不只限於英文，並且應同時使用 MeSH字串及一般檢索詞彙(text words)。

Supporting Document S1 – Search Terms Used

#1 exp metronidazole/
#2 (metronidazol* or Flagyl or Rozex or Metrogel or Anabact or 5-nitroimidazol*).mp.

#3 exp hemorrhoids/
#4 (haemorrhoid$ or hemorrhoid$).mp.
#5 piles.mp.

#6 exp hemorrhoidectomy/
#7 (haemorrhoidectom$ or hemorrhoidectom$).mp.
#8 Milligan morgan.mp.
#9 Ferguson.mp.

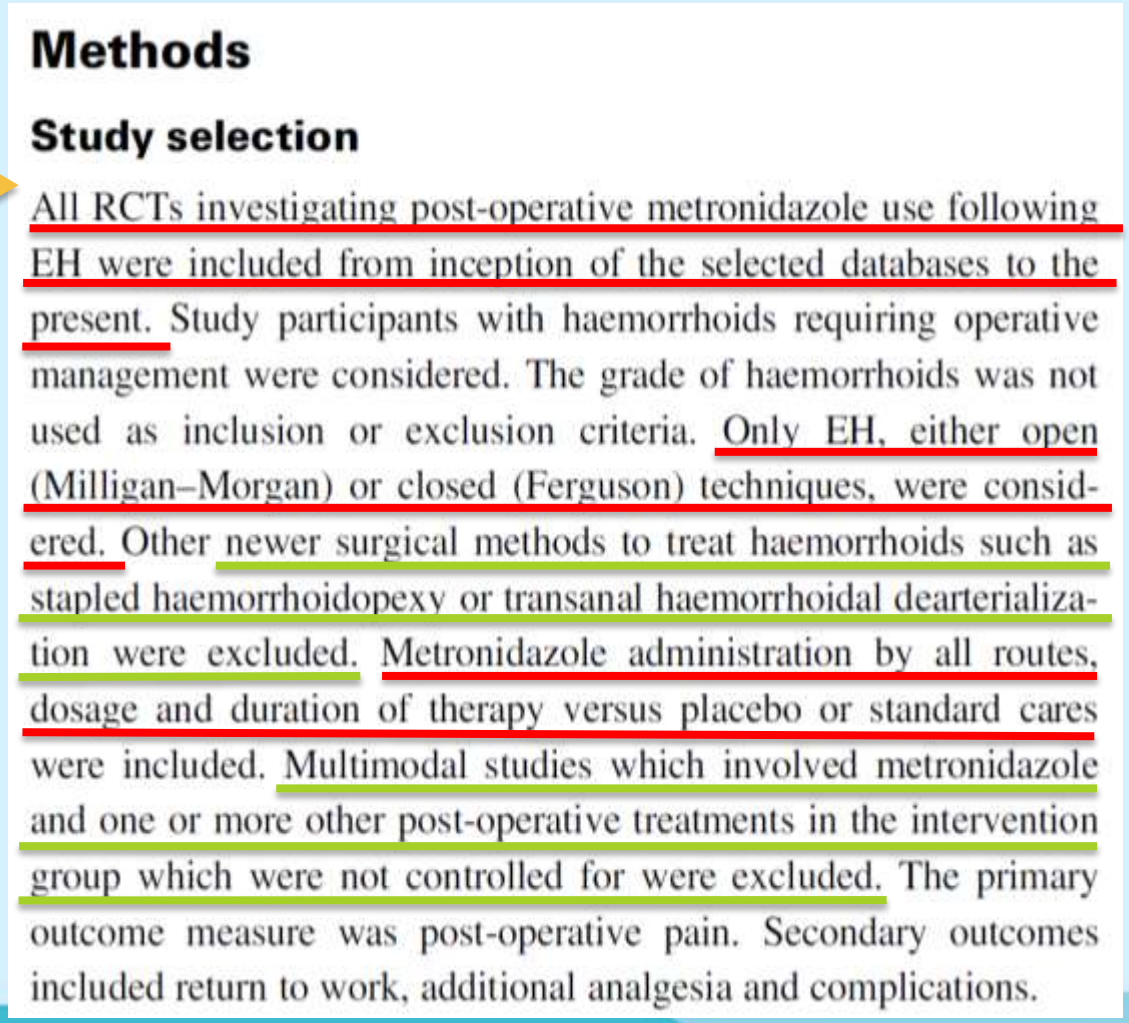
#10 #1 OR #2
#11 #3 OR #4 OR #5
#12 #6 OR #7 OR #8 OR #9
#13 #10 AND #11 AND #12

評讀結果： ○是 ○否 ●不清楚

Appraisal FAITH - 步驟 2：系統性文獻回顧的品質如何(F)

【F】研究是否找到 (Find) 所有的相關證據？

在文章的方法(Methods)章節，可以找到詳細**搜尋策略的說明**，包括使用的名詞，結果(Results)章節中可以找到本篇系統性文獻回顧評估的摘要及全文文獻數目、文獻納入與排除的數量及原因。
資料可能會以圖表或 PRISMA 的流程圖呈現。



Methods

Study selection

All RCTs investigating post-operative metronidazole use following EH were included from inception of the selected databases to the present. Study participants with haemorrhoids requiring operative management were considered. The grade of haemorrhoids was not used as inclusion or exclusion criteria. Only EH, either open (Milligan–Morgan) or closed (Ferguson) techniques, were considered. Other newer surgical methods to treat haemorrhoids such as stapled haemorrhoidopexy or transanal haemorrhoidal dearterialization were excluded. Metronidazole administration by all routes, dosage and duration of therapy versus placebo or standard cares were included. Multimodal studies which involved metronidazole and one or more other post-operative treatments in the intervention group which were not controlled for were excluded. The primary outcome measure was post-operative pain. Secondary outcomes included return to work, additional analgesia and complications.

Appraisal FAITH - 步驟 2：系統性文獻回顧的品質如何(F)

【F】研究是否找到 (Find) 所有的相關證據？

在文章的方法(Methods)章節，可以找到詳細搜尋策略的說明，包括使用的名詞，結果(Results)章節中可以找到本篇系統性文獻回顧**評估的摘要及全文文獻數目、文獻納入與排除的數量及原因**。資料可能會以圖表或 PRISMA 的流程圖呈現。

Results

Study selection

A flowchart showing the selection of articles is presented in Figure 1. A total of nine studies were identified for inclusion in the review. Of the three excluded papers, one was excluded as it compared topical metronidazole versus sucralfate rather than against placebo or standard care.[18] Another investigated prophylactic antibiotics with intra-operative IV metronidazole and ceftriaxone without any post-operative metronidazole use.[19] The third was excluded as it involved intervention patients receiving metronidazole, lactulose and topical glyceryl-trinitrate (GTN) ointment versus placebo.[20]

Flow Diagram - PRISMA

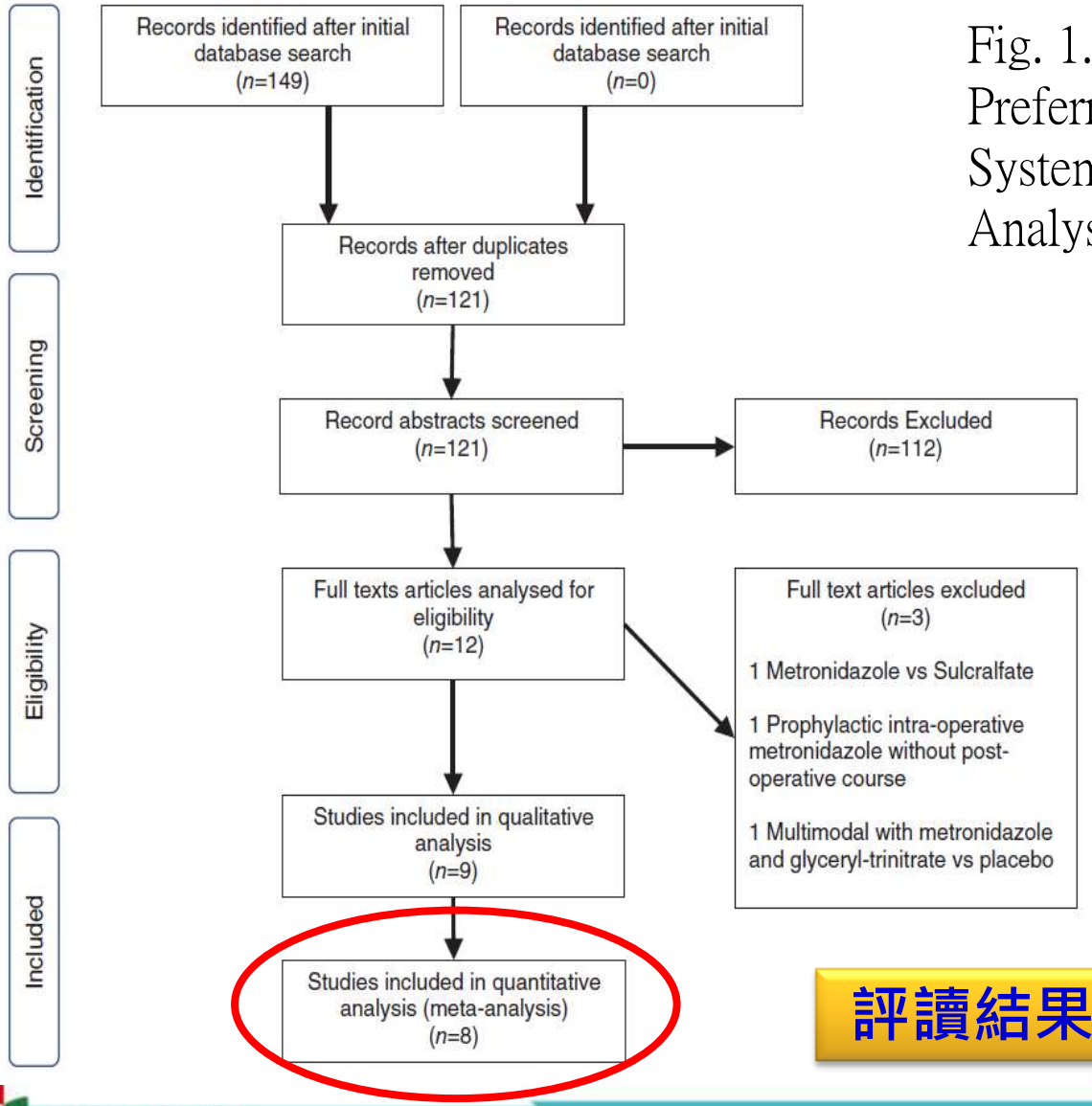


Fig. 1.
Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram.

評讀結果：●是 ○否○不清楚

Appraisal FAITH - 步驟 2：系統性文獻回顧的品質如何(A)

【A】文獻是否經過嚴格評讀 (Appraisal)？

應根據不同臨床問題的文章類型，選擇適合的評讀工具，並說明每篇**研究的品質**(如針對治療型的臨床問題，選用隨機分配、盲法、及完整追蹤的研究類型)。

Risk of bias in individual studies

Risk of bias for each eligible study was determined using the Cochrane Collaboration risk of bias assessment tool for the RCTs. Each reviewer worked independently initially and any disagreements were resolved by consensus.

Appraisal FAITH - 步驟 2：系統性文獻回顧的品質如何(A)

Table 1 Risk of bias

	Random sequence generation	Allocation concealment	Blinding of participants	Blinding of outcome assessment	Incomplete outcome data	Reporting bias	Placebo
Al-Mulhim *et al.* (2006)[23]	Low	Unclear	High	Unclear	High	Low	Unclear
Ala *et al.* (2008)[24]	Low	Unclear	Low	Low	Unclear	Low	Yes
Balfour *et al.* (2002)[25]	Low	Low	Low	Low	Low	High	Yes
Basso *et al.* (2011)[26]	Low	Low	Low	Unclear	Low	Low	Unclear
Carapeti *et al.* (1998)[7]	Low	Low	Low	Low	Low	Low	Yes
Ng *et al.* (2006)[27]	Low	Low	High	Low	Low	Low	Yes
Nicholson and Armstrong (2004)[11]	Low	Low	Low	Low	Low	Low	Yes
Pourghassem *et al.* (2012)[21]	Low	Unclear	Low	Low	Low	Low	Yes
Solorio-López *et al.* (2015)[28]	Low	Low	Low	Unclear	High	Low	Yes

評讀結果：●是 ○否○不清楚

Appraisal FAITH步驟 2：系統性文獻回顧的品質如何 (I)

【I】是否只納入 (Included) 具良好效度的文章？

僅進行文獻判讀是不足夠，系統性文獻回顧只納入至少要有一項研究結果是極小偏誤的試驗。在文章的方法章節，可以找到文章評估的方式，及由誰完成評估的，在結果章節則會提供審查者意見一致性的程度。

Study selection

Study eligibility assessment was performed independently by two reviewers (W.X. and J.P.R.M.). Any disagreements were resolved by consensus.

Data extraction

A predefined database, based on the Cochrane Data Collection Form for Intervention Studies was utilized to extract data. Both reviewers (W.X. and J.P.R.M.) independently carried out data extraction on all included data. Disagreements were resolved via consensus between the two reviewers. In cases where data were unavailable, all attempts were made to contact the original authors.

評讀結果： ●是 ○否○不清楚

Appraisal FAITH步驟 2：系統性文獻回顧的品質如何 (T)

Author (Year)	Setting	Randomisation Method	Blinding	Metronidazole (Oral or Topical)	Approach	N (No. in Metronidazole Group)	Mean Age, Sex (%M)	Grade	VAS Measured Up To
Al-Mulhim (2006)	Saudi Arabia	Not specified	Unclear	Oral 500mg TDS for 3 days	Open	200§ (100)	47.5 41.0%	III, IV	7 days
Ala (2008)	Iran	Not specified	Double	Topical 10% TDS	Open	47 (25)	37.5 25.5%	II, III, IV	14 days
Balfour (2002)	United Kingdom	Computer	Double	Oral 400mg TDS for 7 days	Closed	38 (18)	56.1 42.1%	II, III	14 days
Basso (2011)	Brazil	Random numbers	Double	Topical 10% TDS	Hybrid‡	42 (21)	47.7 45.2%	-	28 days
Carapeti (1998)	United Kingdom	Random numbers	Double	Oral 400mg TDS for 7 days	Open	40 (20)	49.0 42.5%	-	7 days
Ng (2006)	Hong Kong	Sealed envelope	None	Oral 400mg TDS for 7 days†	Open	52 (26)	49.4 30.8%	III, IV	2 days
Nicholson (2004)	United States of America	Coin Toss	Single	Topical 10% TDS	Closed	20 (10)	48.1 65.0%	III, IV	28 days
Pourghassem (2012)	Iran	Computer	Double	Topical 7.5% TDS	Open	40 (20)	29.5 100%‖	-	1 day
Solorio-Lopez (2015)	Mexico	Sealed envelope	Unclear	Oral 500mg TDS for 7 days	Closed	44 (22)	46.3 63.6%	III, IV	14 days

Appraisal FAITH步驟 2：系統性文獻回顧的品質如何 (T-H)

【T】作者是否以表格和圖表「總結」(Total up) 試驗結果？
【H】試驗的結果是否相近 - 異質性 (Heterogeneity)？

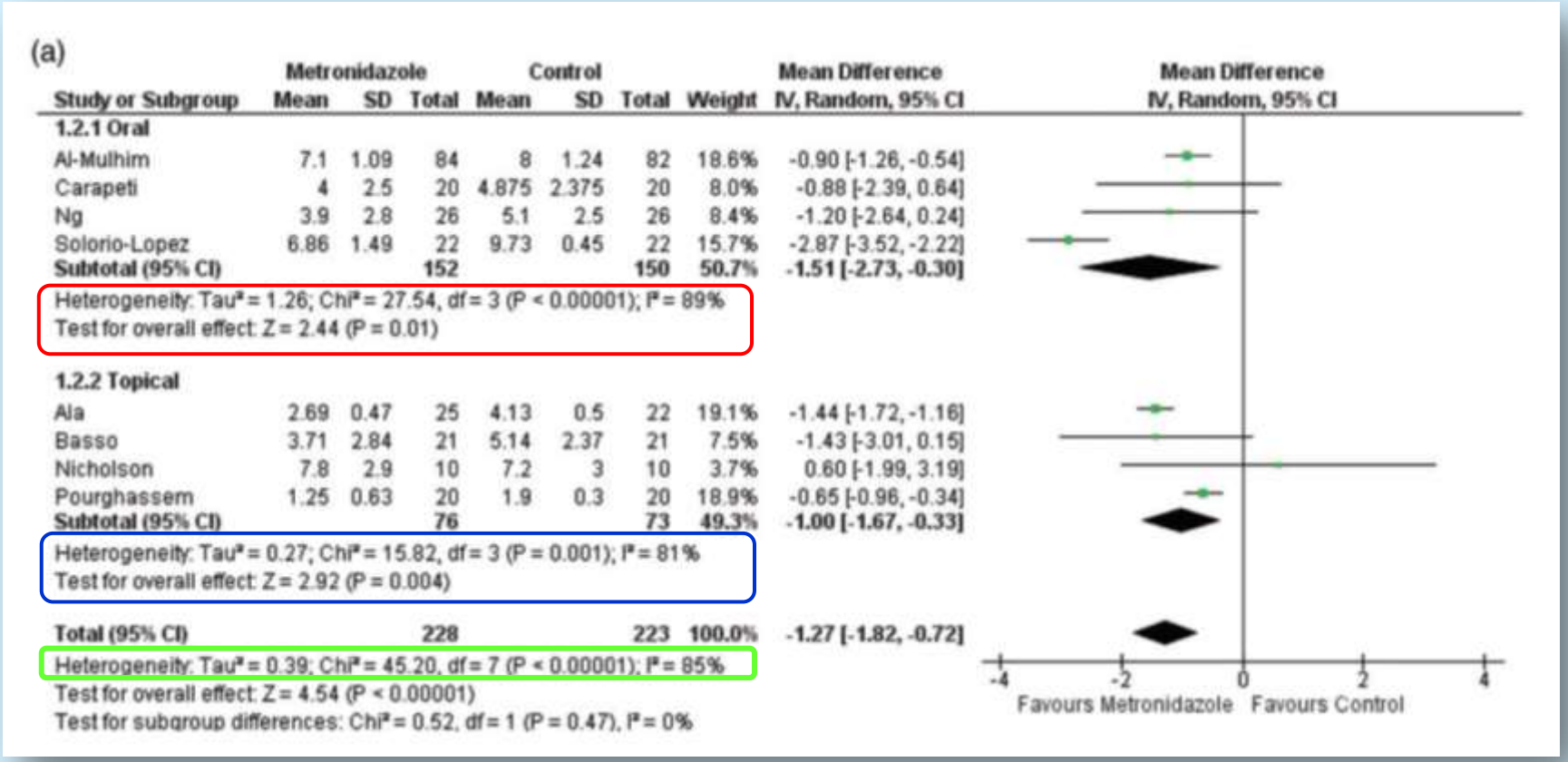


Fig. 2 Visual analogue score at post-operative days 1, 7 and 14.

Appraisal FAITH步驟 2：系統性文獻回顧的品質如何 (T-H)

【T】作者是否以表格和圖表「總結」(Total up) 試驗結果？
【H】試驗的結果是否相近 - 異質性 (Heterogeneity)？

(b)

Study or Subgroup	Metronidazole Mean	SD	Total	Control Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
1.8.1 Oral								
Al-Mulhim	0.8	0.21	84	2.6	0.65	82	25.8%	-1.80 [-1.95, -1.65]
Carapeti	2.9	1.75	20	4.25	1.75	20	15.6%	-1.35 [-2.43, -0.27]
Solorio-Lopez	3.14	1.03	22	7.36	1.39	22	20.1%	-4.22 [-4.94, -3.50]
Subtotal (95% CI)			126			124	61.4%	-2.47 [-4.12, -0.82]
Heterogeneity: Tau² = 1.99; Chi² = 42.28, df = 2 (P < 0.00001); I² = 95%								
Test for overall effect: Z = 2.93 (P = 0.003)								
1.8.2 Topical								
Ala	1.31	0.36	25	2.83	0.54	22	25.1%	-1.52 [-1.79, -1.25]
Nicholson	3.4	1.3	10	6.3	1.6	10	13.5%	-2.90 [-4.18, -1.62]
Subtotal (95% CI)			35			32	38.6%	-2.06 [-3.38, -0.74]
Heterogeneity: Tau² = 0.73; Chi² = 4.29, df = 1 (P = 0.04); I² = 77%								
Test for overall effect: Z = 3.06 (P = 0.002)								
Total (95% CI)			161			156	100.0%	-2.29 [-2.97, -1.62]
Heterogeneity: Tau² = 0.45; Chi² = 50.75, df = 4 (P < 0.00001); I² = 92%								
Test for overall effect: Z = 6.68 (P < 0.00001)								
Test for subgroup differences: Chi² = 0.14, df = 1 (P = 0.71), I² = 0%								

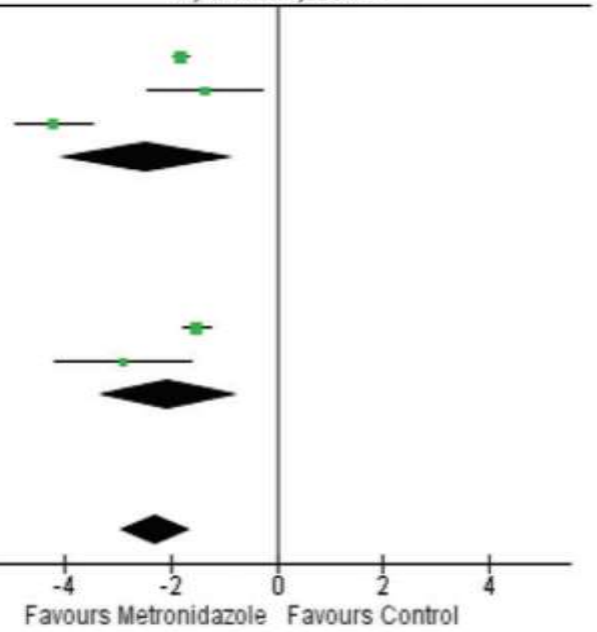


Fig. 2. Visual analogue score at post-operative days 1, 7 and 14.

Appraisal FAITH步驟 2：系統性文獻回顧的品質如何 (T-H)

【T】作者是否以表格和圖表「總結」(Total up) 試驗結果？
【H】試驗的結果是否相近 - 異質性 (Heterogeneity)？

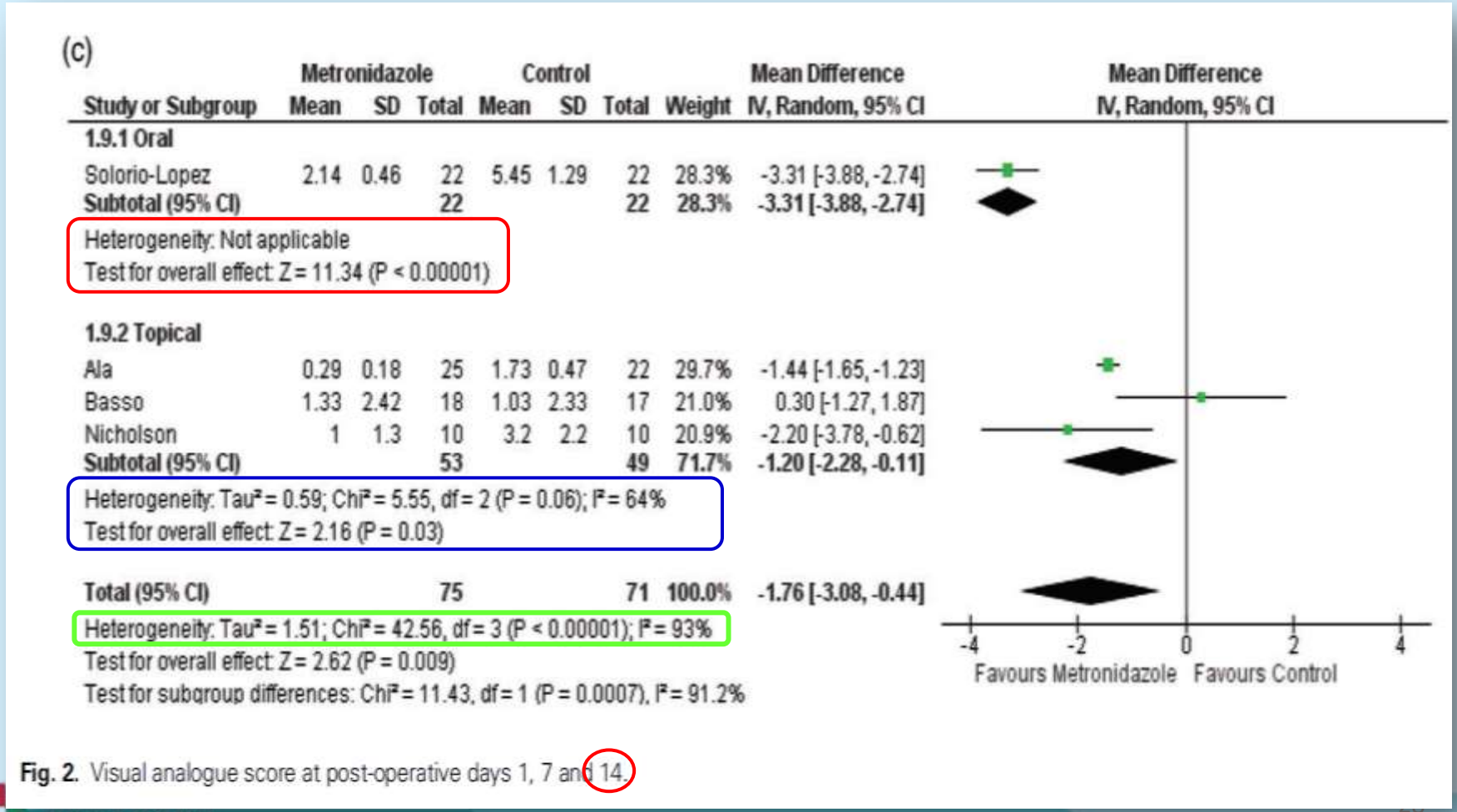


Fig. 2. Visual analogue score at post-operative days 1, 7 and 14.

Appraisal FAITH步驟 2：系統性文獻回顧的品質如何 (T-H)

- **Secondary outcome：Return to normal activity**
  - Five studies, all in the oral metronidazole subgroup.
  - Significant MD in earlier return to work favoring intervention (MD = −4.49 days, 95% CI [−7.70, −1.28], P = 0.006).
  - Heterogeneity was encountered (I^2 = 88%, P < 0.00001)

Appraisal FAITH步驟 2：系統性文獻回顧的品質如何 (T-H)

- **Secondary outcome：Complications**
  - Overall: no significant difference (OR = 0.40, 95% CI [0.15, 1.04], P = 0.06).
  - Moderate heterogeneity (I^2 = 56%).
  - Urinary retention: no significant difference (OR = 0.58, 95% CI [0.21, 1.63], P = 0.30), no heterogeneity (I^2 = 0%)

Appraisal FAITH步驟 2：系統性文獻回顧的品質如何 (T-H)

- **Secondary outcome：Complications**
  - Perianal paresthesia
  - Bleeding
    - Paucity of data resulted in an inability to meta-analysis these results but no study identified a difference between metronidazole and placebo.

Appraisal FAITH步驟 2：系統性文獻回顧的品質如何 (T-H)

- **Secondary outcome：Analgesia consumption**
  - No uniform standard of analgesia intra- or post-operatively.
  - Postoperative as needed rescue analgesia also varied considerably between studies in terms of type of analgesic, dose and frequency.
  - Two studies (Ala et al. & Solorio-López et al.) found a significant difference, the metronidazole group.

Appraisal sheets(FAITH)

- Appraisal Tool
  - [統合分析 Meta-analysis]
    - 步驟1：研究探討的問題為何 (PICO)
    - 步驟2：研究的品質如何 (內在效度)
    - 步驟3：研究結果之意義為何 (效益)

Appraisal FAITH 系統性文獻回顧快速評讀表

➢ 步驟 3：研究結果之意義為何 (效益)

- ✓ Reduction of pain from days 1 to 14 in the metronidazole group.
- ✓ Both oral and topical routes of administration resulted in benefit.
- ✓ Significantly earlier return to normal activity of nearly 5 days.
- ✓ None of the identified studies commented on any significant side effect profiles for either route.

Discussion

Supporting Table S2 – Perioperative Standard Care

Author (Year)	Standard care received	
		Analgesia Regimen
Al-Mulhim (2006)	Castor oil 2ml daily 2 days pre-op Lactulose 20ml BD 2 weeks post-op	Diclofenac 50mg TDS Xylocaine 2% ointment TDS
Ala (2008)	Milk of magnesia 15ml TDS post-op	Analgesia as needed post-op, not specified
Balfour (2002)	Lactulose 20ml BD	Codeine 30mg + Paracetamol 500mg PRN Diclofenac 50mg PRN
Basso (2011)	Pre-op enema Nifedipine 0.3% Sitz baths with potassium permanganate 20 minutes TDS	Dipyrone 1g PO if mild pain up to 4 times daily Ketorolate 10mg sublingual if severe pain or dipyrone refractoriness up to 4 times daily
Carapeti (1998)	Lactulose 20ml BD 2 days pre-op and 2 weeks post-op Glyceryl-trinitrate 0.2% TDS 2 weeks post-op	Diclofenac suppository 100mg administered at end of procedure Diclofenac 50mg TDS for 1 week, topical Nefopam 60mg TDS in 2 patients due to diclofenac contra-indication Paracetamol and co-dydramol PRN
Ng (2006)		Oral Dologesic (dextropropoxyphene 32.5 mg paracetamol 320 mg) IM pethidine (1 mg/kg) on demand
Nicholson (2004)	Psyllium BD Mineral oil 30ml Daily	Hydrocodone 10mg PRN
Pourghassem (2012)		Morphine IV on demand
Solorio-Lopez (2015)	Psyllium 10g Daily	Oral paracetamol 1g TDS Oral diclofenac 100mg BD

Discussion

- 術前一天或手術當天住院，平均住院天數2-3天。
- 手術當天早上6點清腸。
- 術後標準照護:
  - 止痛藥物: Ponstan / Keto 1# po QID
  - 止痛針劑: Morphine / Dynastat PRN
  - 嚴重疼痛或NSAID過敏或禁忌: Ultracet or Paramol
  - 軟便劑: MgO 1-2# po QID, Sennoside 2# po HS
  - 習慣性便祕: Lactulose 15-20ml QD-BID
  - 藥膏: Proctosedyl, Xylocain… (視情況給予)

討論：使用Metronidazole是否可以改善痔瘡術後疼痛問題？

同意(綠牌)：14位
仍有疑慮(黃牌)：16位
不同意(紅牌)：2位