

ANALYZING DATA

Egyptian Cochrane network

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References

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<http://www.cochrane-handbook.org>

Cochrane Handbook for Systematic Reviews of Interventions:
Chapter 9: Analysing data and undertaking meta-analyses

<http://www.cochrane-net.org/openlearning>

Cochrane Collaboration Open Learning Material for
Reviewers

To Join The Cochrane Collaboration contact

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Steps of a Systematic Review

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- .. Well formulated question
- .. Comprehensive search
- .. Unbiased selection
- .. Critical appraisal
- .. Analysis

Steps of a meta analysis

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- .. Extract outcome data from each study
- .. Calculate the treatment effect for each outcome in each study
- .. Calculate a pooled result of treatment effect for each outcome in all studies
- .. Present the results in a forest plot

Types of data

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- .. dichotomous (binary) data
- .. continuous data
- .. ordinal data including scales
- .. counts
- .. time-to-event (typically survival)

Dichotomous (binary) data

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Measures of
treatment
effect

- relative

- ✘ the risk ratio (RR) (the relative risk)
- ✘ the odds ratio (OR)

- Absolute

- ✘ the risk difference (RD) (the absolute risk reduction)
- ✘ the number needed to treat (NNT)

Risk and Odds

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- .. In general conversation
- .. In analysis
 - ⊗ When the difference between them is ignored, the results are misinterpreted.

Risk and Odds

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Risk

physicians

event/ total

is expressed as a decimal number between 0 and 1

Odds

gamblers

event/ without event

can be any value from 0 to ∞ . It is expressed as a ratio of two integers

Risk Ratio and Odds Ratio

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Practical points

- For both measures a value of 1 indicates that treatment has NO effect
- Neither can be calculated if there is no events in the control group

Warning: OR and RR are not the same

RD (ARR)

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Risk Difference (Absolute Risk Reduction)

- can be calculated even when there are no events in either group.
- is easy to interpret

Number Needed to Treat (NNT)

- $NNT = 1/ARR$

Number Treated Needlessly (NTN)

- $NTN = NNT - 1$

Calculation

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	Wound infection	no infection	total
AB	20	80	100
placebo	80	20	100

Risk of infection

Odds of infection

0.2 (20%)

0.25 (1:4)

0.8 (80%)

4 (4:1)

RR 0.25

RD -0.6 (-60%)

OR 0.0625

Warning: OR and RR are NOT the same

Calculation

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	Wound infection	no infection	total
AB	2	98	100
placebo	8	92	100

Risk of infection

0.02 (2%)

0.08 (8%)

RR 0.25

RD -0.06 (-6%)

RR and RD

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	AB	placebo	RR	RD
study 1	20/100	80/100	0.25	-60%
Study 2	2/100	8/100	0.25	-6%

RD discriminates between small and large treatment effects

Continuous data

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- .. we can use the same statistical methods for other types of data, e.g. measurement scales
- .. Measures of treatment effect
 - ⊗ Mean Difference (difference in means)
 - n is a standard statistic that measures the absolute difference between the mean value in two groups in a clinical trial.

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Cesarean Delivery

Evidence based versus Eminence Based Practice

Techniques for CS

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- .. Examine the results
- .. Interpret results
- .. Provide statement of evidence

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Evidence Based Cesarean

Pre Operative Preparation

Anesthesia

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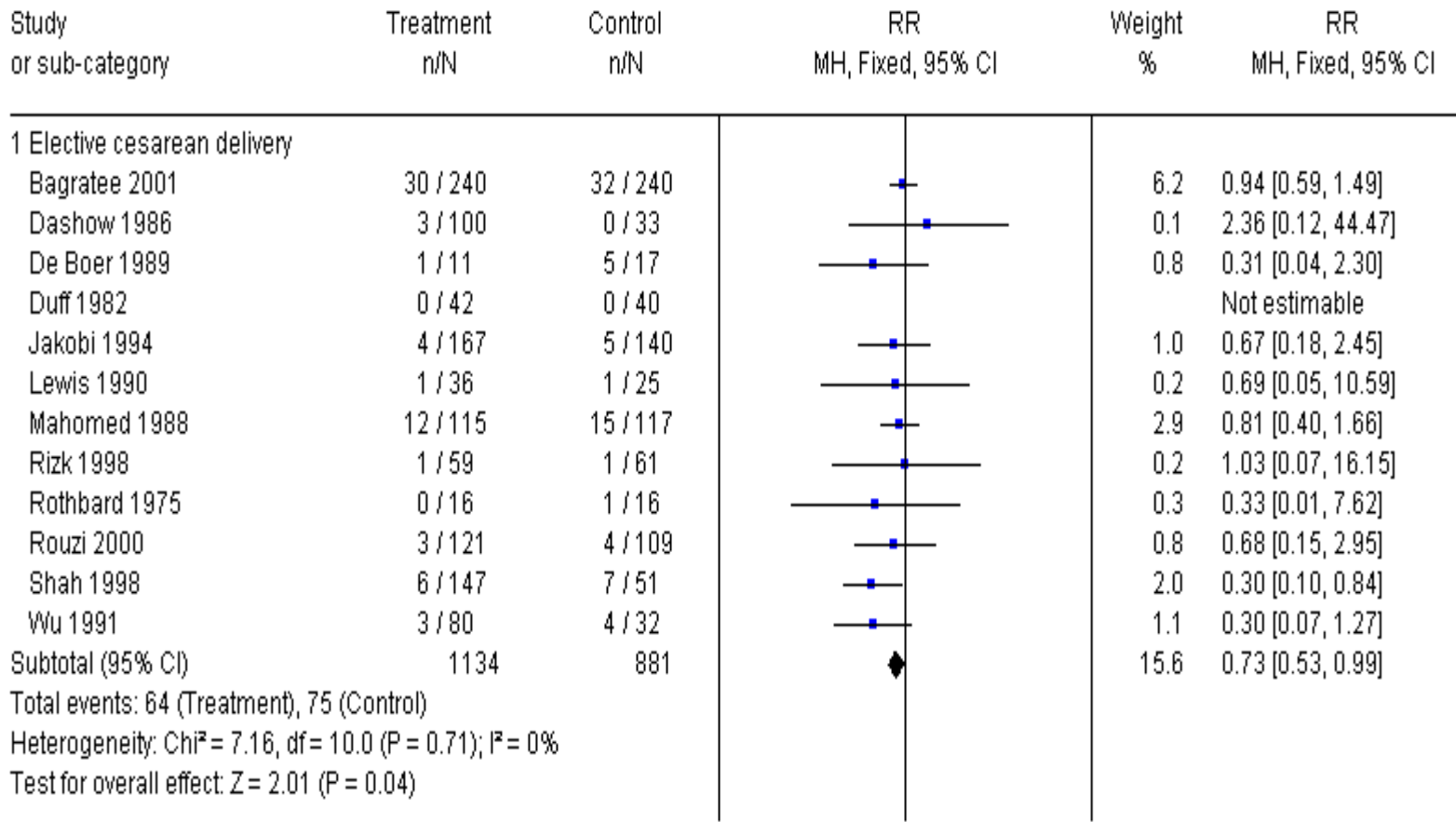
- .. Regional versus general anesthesia
- .. blood loss is reduced with the use of regional anesthesia
- .. client satisfaction is better with general anesthesia

Prophylactic Antibiotics

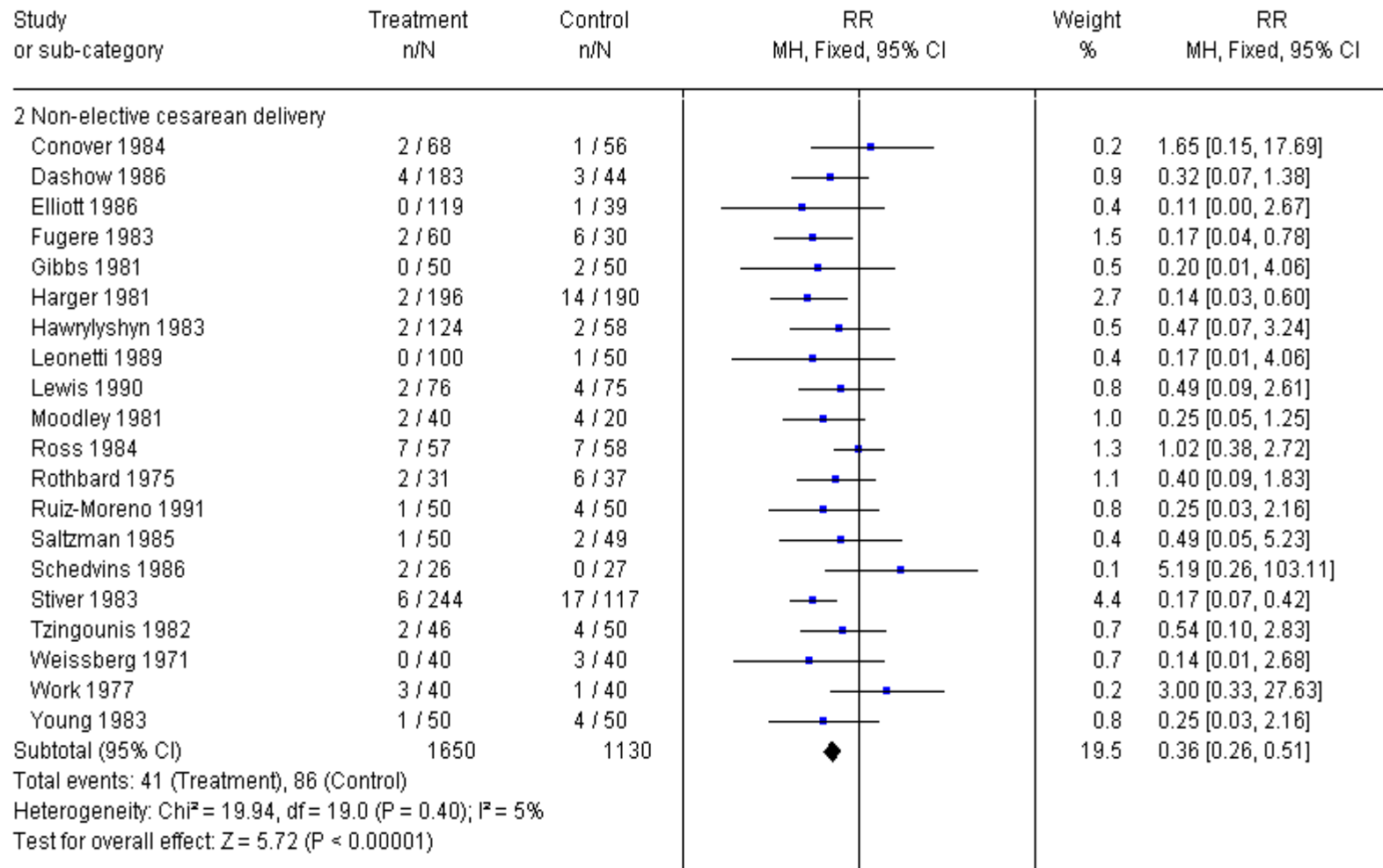
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- .. Treatment effect
- .. Single versus multiple doses
- .. Timing (pre, intra, post operative)

Comparison: 1 Prophylactic antibiotics in cesarean section
 Outcome: 2 Wound infection

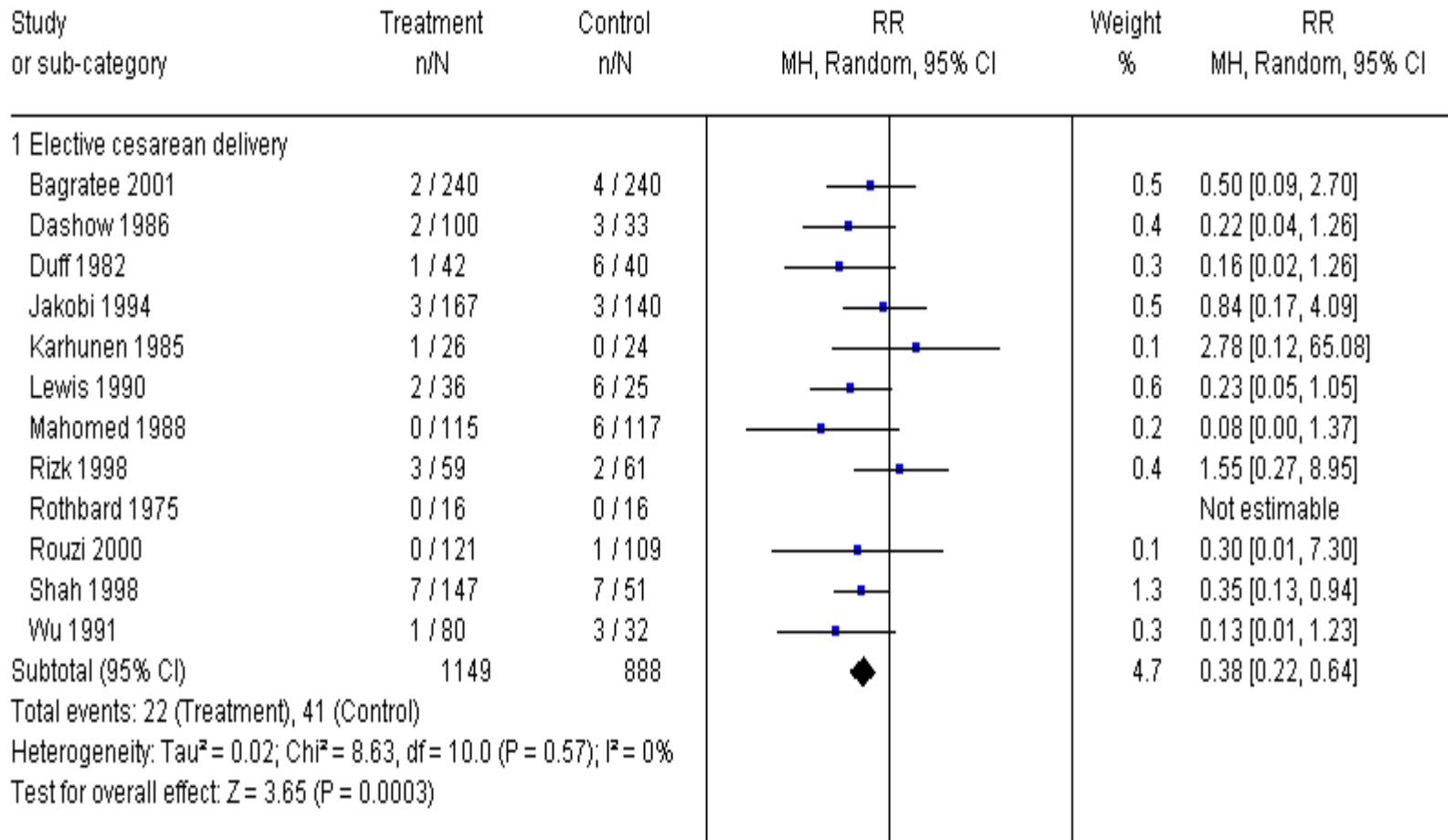


Comparison: 1 Prophylactic antibiotics in cesarean section
 Outcome: 2 Wound infection

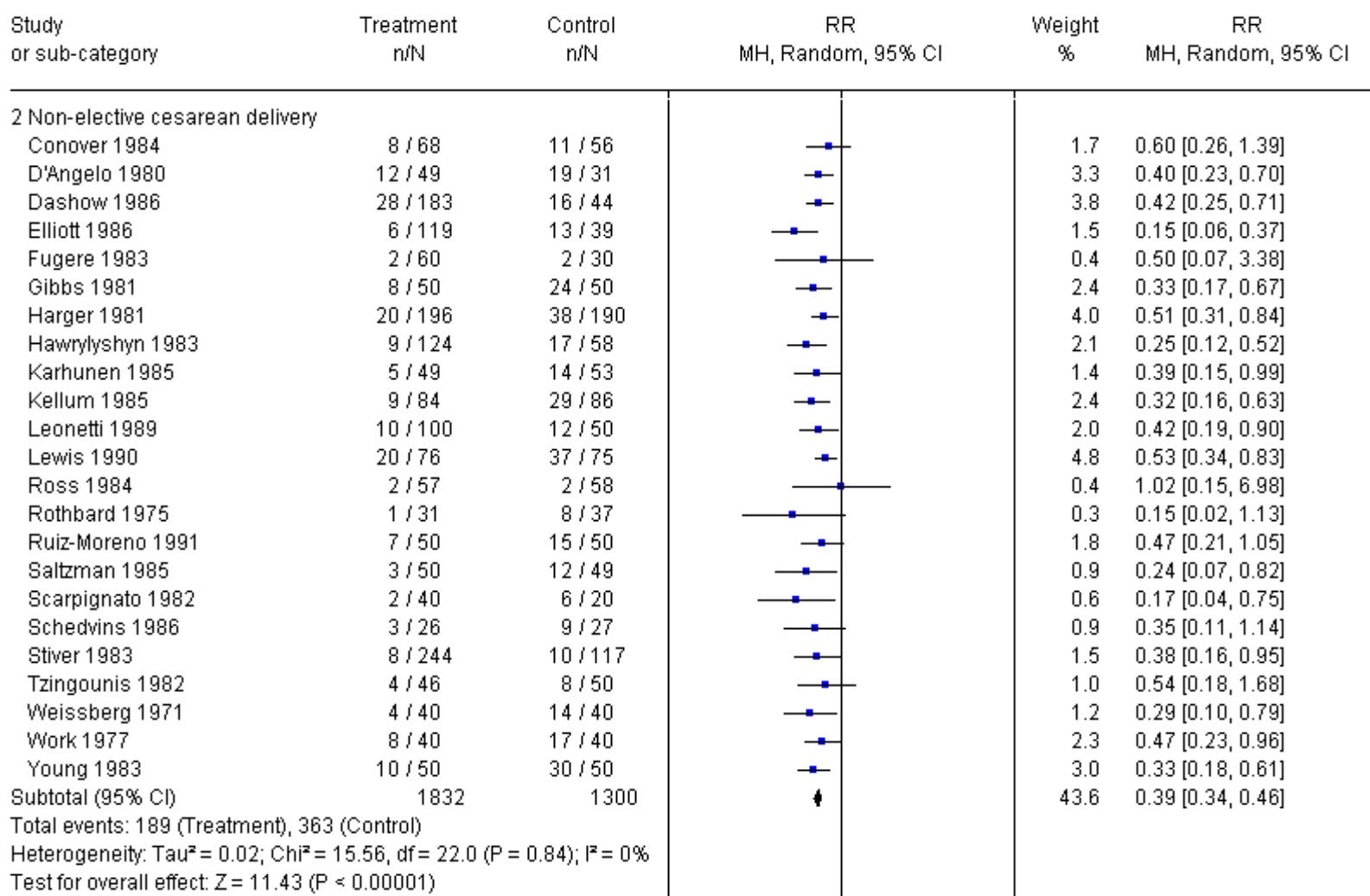


Comparison: 1 Prophylactic antibiotics in cesarean section

Outcome: 3 Endometritis



Comparison: 1 Prophylactic antibiotics in cesarean section
 Outcome: 3 Endometritis



Antibiotic prophylaxis

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	Endometritis	Wound Infection
RR	0.39	0.41
Baseline Risk	18%	10%
ARR	7%	4%
NNT	14	26

Single vs Multiple doses

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.. Endometritis

- ✧ 14 RCTs (4348 CS)
- ✧ OR 0.92 [0.70, 1.23]

.. Wound Infection

- ✧ 11 RCTs (2531 CS)
- ✧ OR 0.91 [0.58, 1.43]

Practical Points

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- .. We recommend AB to prevent endometritis and wound infection in CS
- .. single or multiple doses are equally effective

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Evidence Based Cesarean

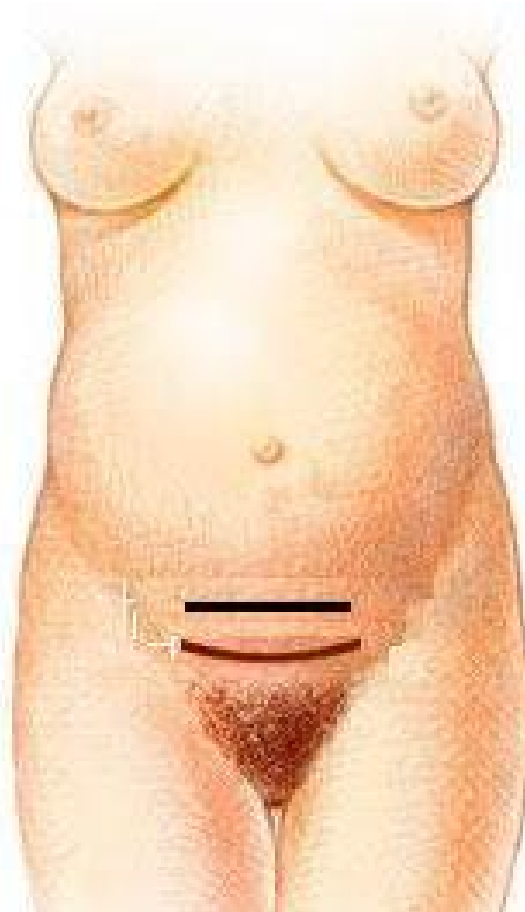
Handling the Anterior Abdominal Wall

choice of incision

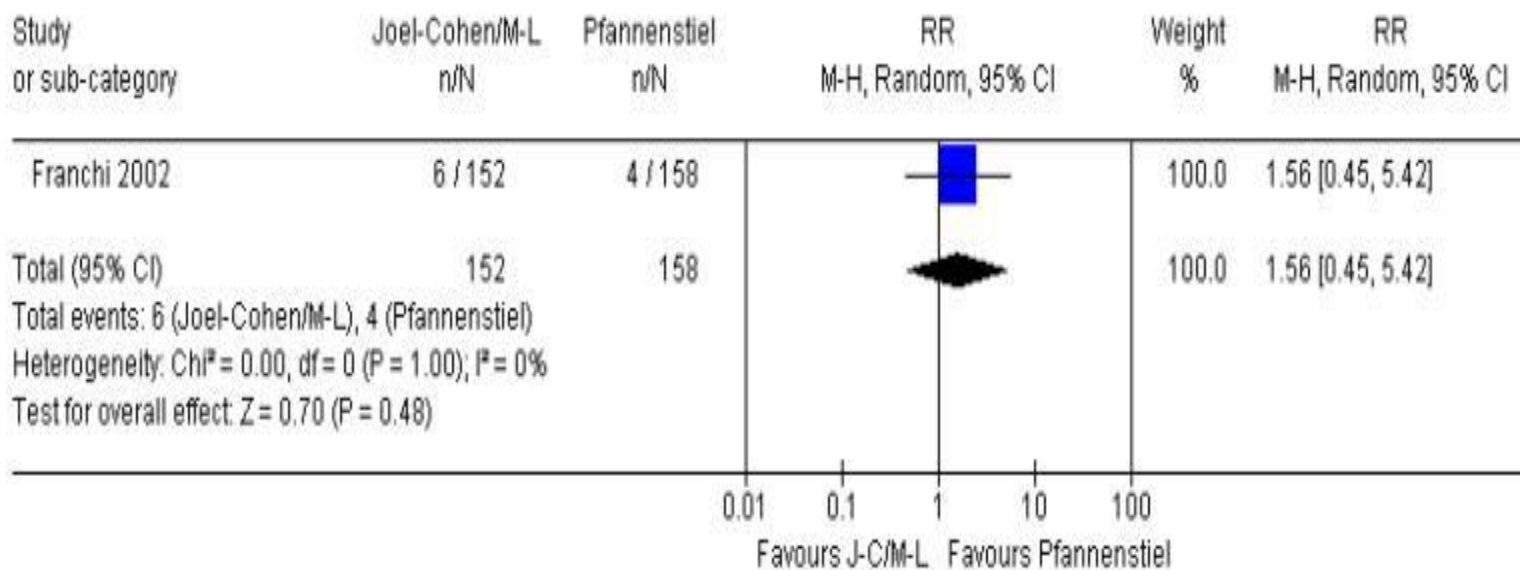
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JC incision

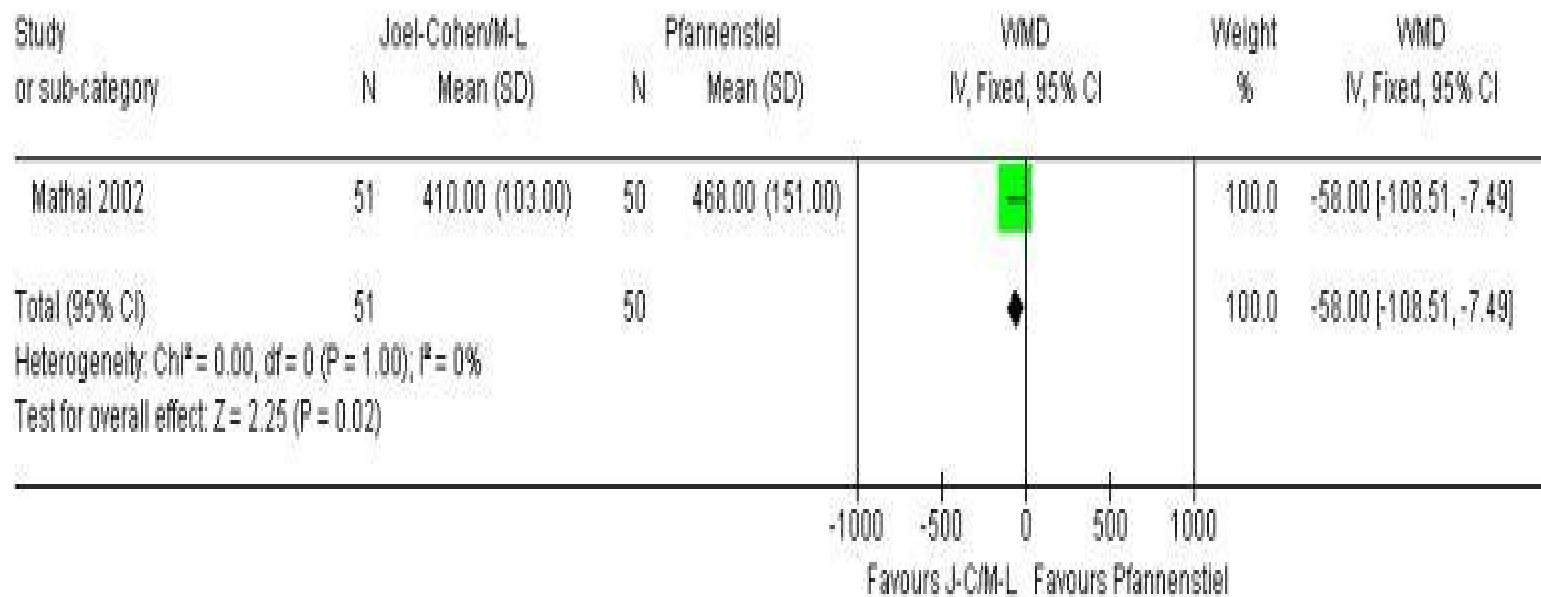
Pfannenstiel
incision



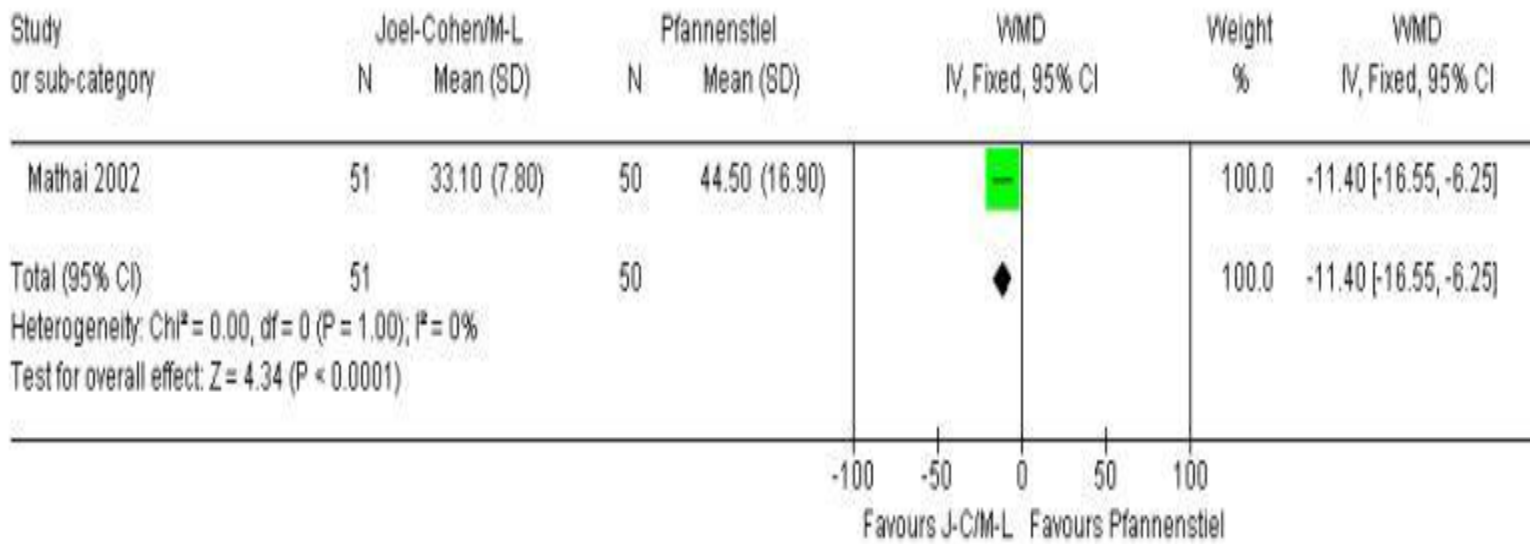
Comparison: 01 Joel-Cohen versus Pfannenstiel incision
 Outcome: 13 Wound infection as defined by trial authors



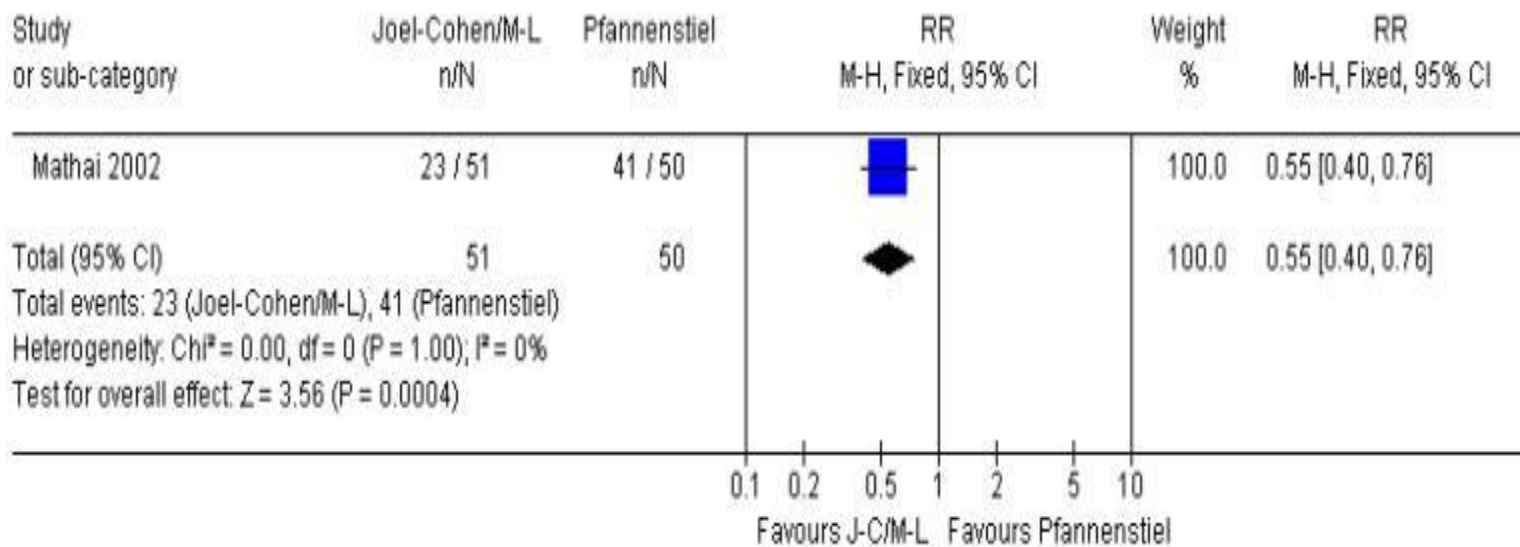
Comparison: 01 Joel-Cohen versus Pfannenstiel incision
 Outcome: 09 Estimated blood loss (mL)



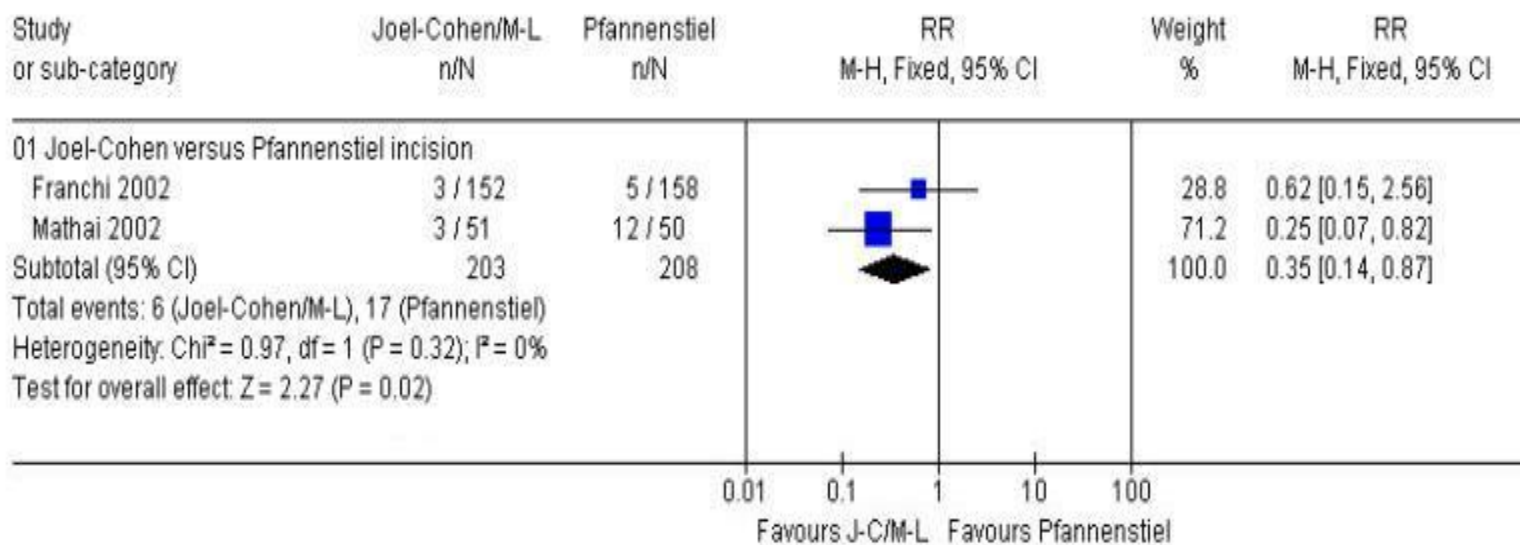
Comparison: 01 Joel-Cohen versus Pfannenstiel incision
 Outcome: 20 Total operative time (minutes)



Comparison: 01 Joel-Cohen versus Pfannenstiel incision
 Outcome: 02 Postoperative analgesia on demand



Comparison: 01 Joel-Cohen versus Pfannenstiel incision
 Outcome: 01 Postoperative febrile morbidity

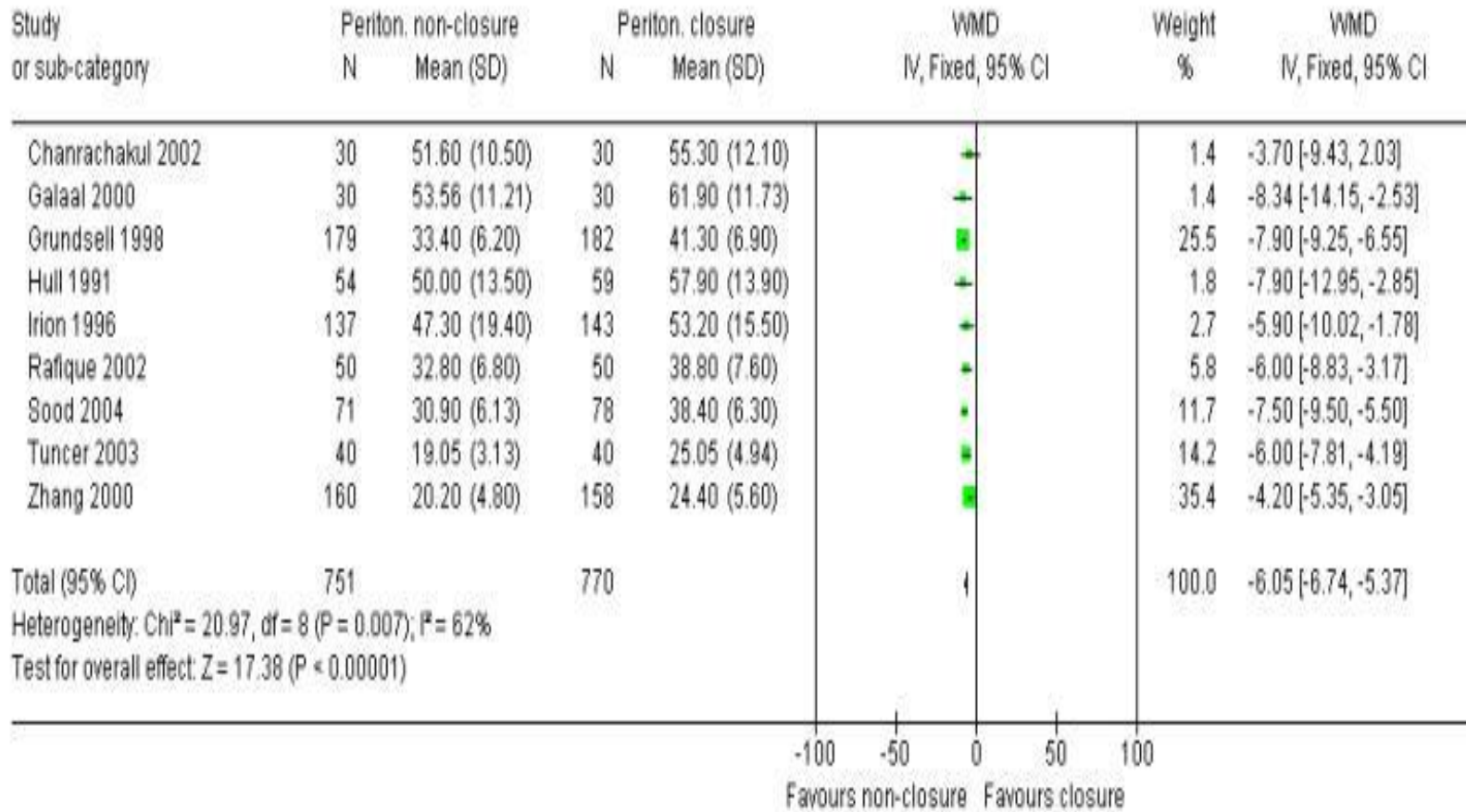


JC vs Pfannenstiel

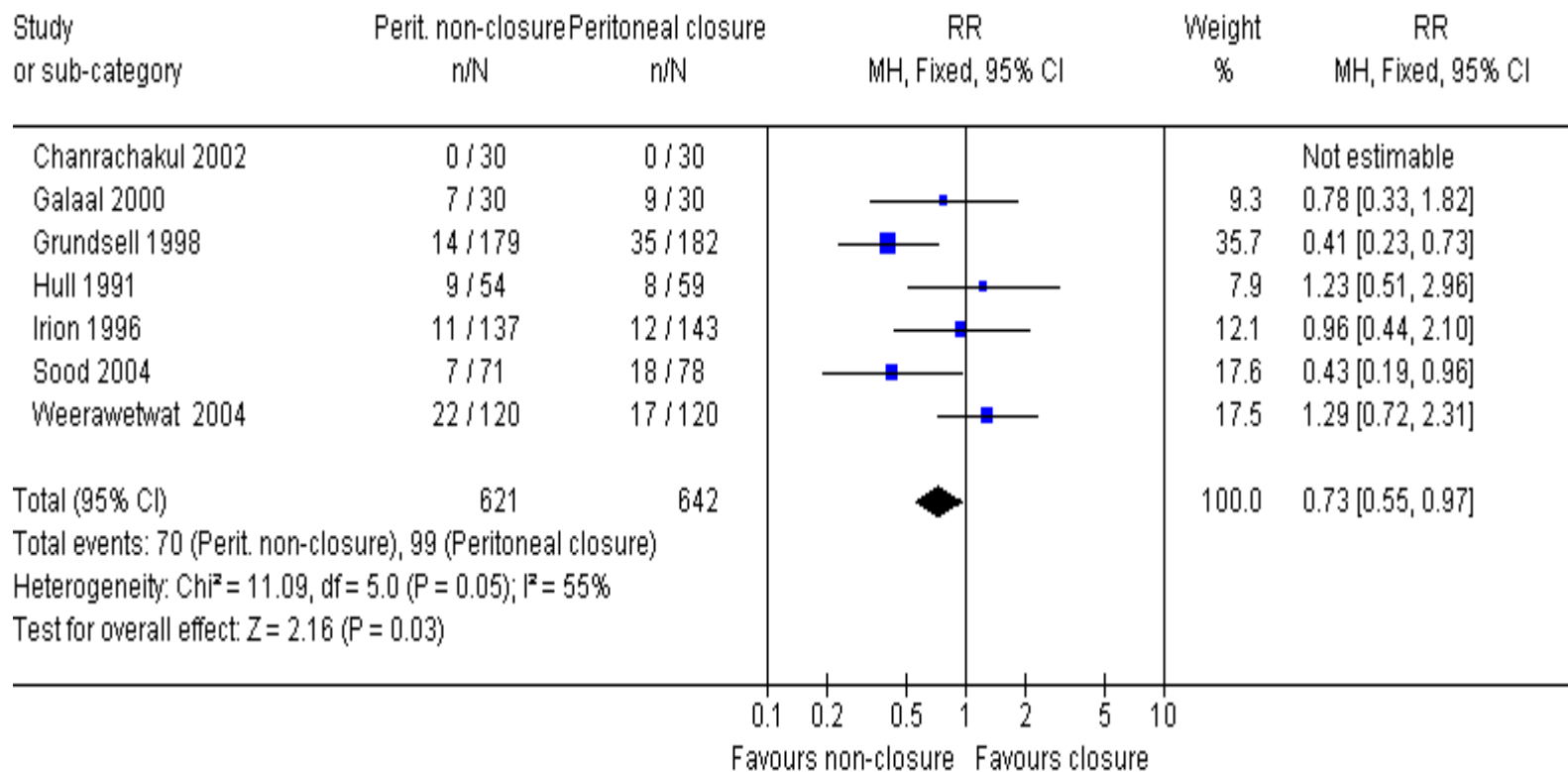
35

- .. The JC incision has advantages compared to the Pfannenstiel incision. These are
 - ✧ less fever
 - ✧ Less analgesic requirements
 - ✧ less blood loss
 - ✧ shorter duration of surgery
- .. Only one trial reported long-term outcomes

Comparison: 01 Non-closure of both parietal and visceral peritoneum versus closure of both peritoneal layers
 Outcome: 01 Operating time (minutes)



Comparison: 1 Non-closure of both parietal and visceral peritoneum versus closure of both peritoneal layers
 Outcome: 3 Postoperative fever



The peritoneum

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- .. evidence suggests that leaving the peritoneum unsutured is of more benefit in
 - ⊗ The short term
 - ⊗ The long-term : decrease adhesions
- .. No evidence to justify peritoneal closure, except in the context of RCT to evaluate long-term outcomes.

The rectus muscle

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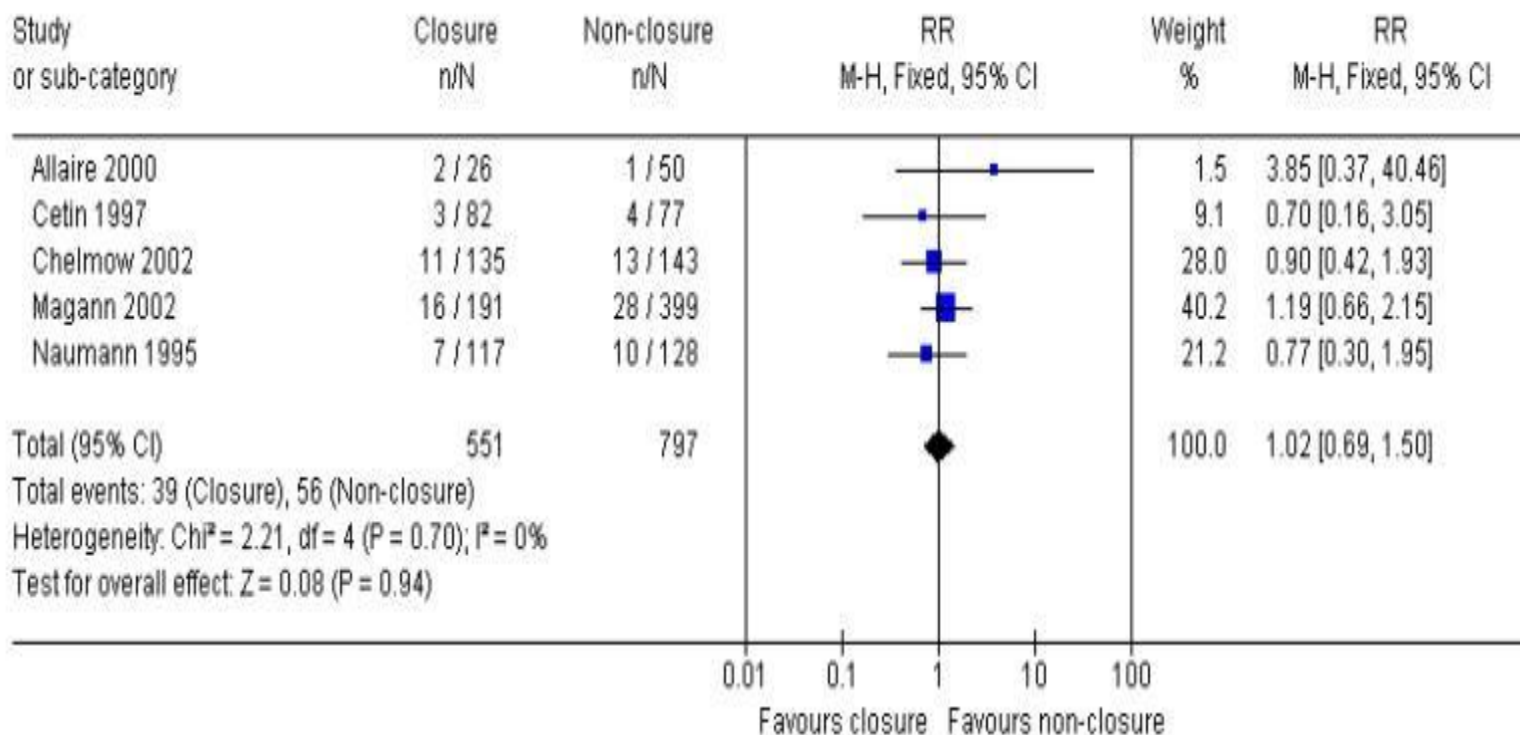
- .. Expert panels agree that the muscles find the right anatomic location postoperatively and that suturing them together can cause unnecessary pain when the woman starts to move after surgery

The Fascia

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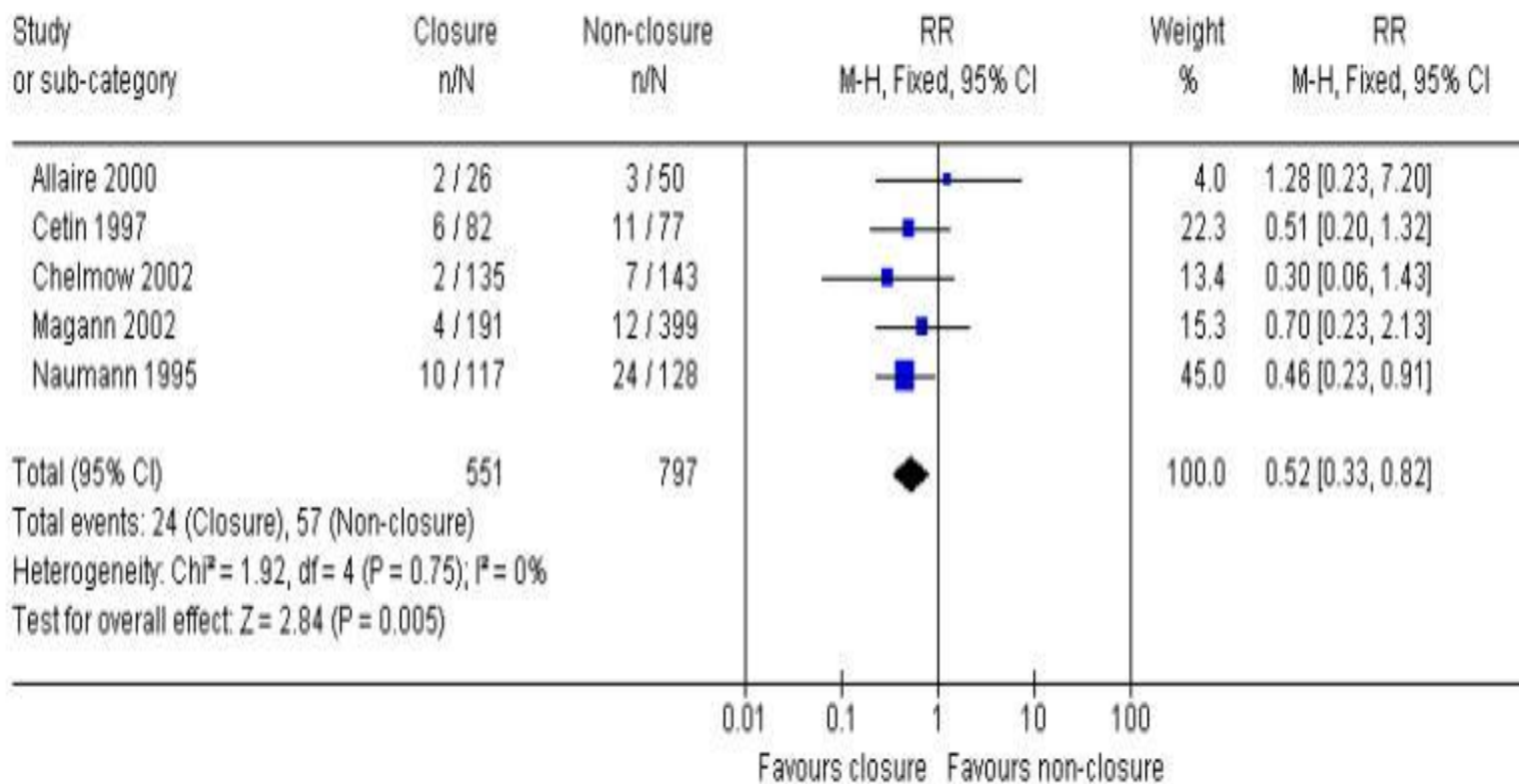
- .. Most experts suggest continuous nonlocking closure with delayed-absorbable suture

Comparison: 01 Closure of subcutaneous tissue versus non-closure of subcutaneous tissue
 Outcome: 01 Wound infection



Comparison: 01 Closure of subcutaneous tissue versus non-closure of subcutaneous tissue

Outcome: 02 Haematoma +/- seroma



The SC tissue

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- Drains (SC or SubFascial) vs No drains
 - ⊗ No difference in the risk of wound infection, other wound complications, febrile morbidity or endometritis
- Closure vs non closure of SC tissue
 - ⊗ No difference in wound infection
 - ⊗ Closure might reduce seroma and/or hematoma

The Skin

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•• Techniques of skin closure

⌘ No difference between

- n sub-cuticular closure using absorbable sutures;
- n sub-cuticular closure using non-absorbable sutures;
- n interrupted stitches using absorbable sutures;
- n interrupted stitches using non-absorbable sutures;
- n staples and clips.

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Evidence Based Cesarean

Handling the uterus

Handling the uterus

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- .. Uterine incision type
- .. Expansion of uterine incision
- .. Instrumental delivery
- .. Placental removal
- .. Uterine exteriorization
- .. Cleaning any placental remnants clots
- .. Manual dilatation of the cervix
- .. Closure of uterine incision
- .. Intra-peritoneal irrigation
- .. packs or towels into the peritoneal cavity

Uterine incision

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- The transverse incision in the lower uterine segment is recommended by experts and by retrospective studies.

Expansion of uterine incision

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- .. Blunt versus sharp
- .. 1 RCT including 945 women
- .. Blunt expansion reduced blood loss

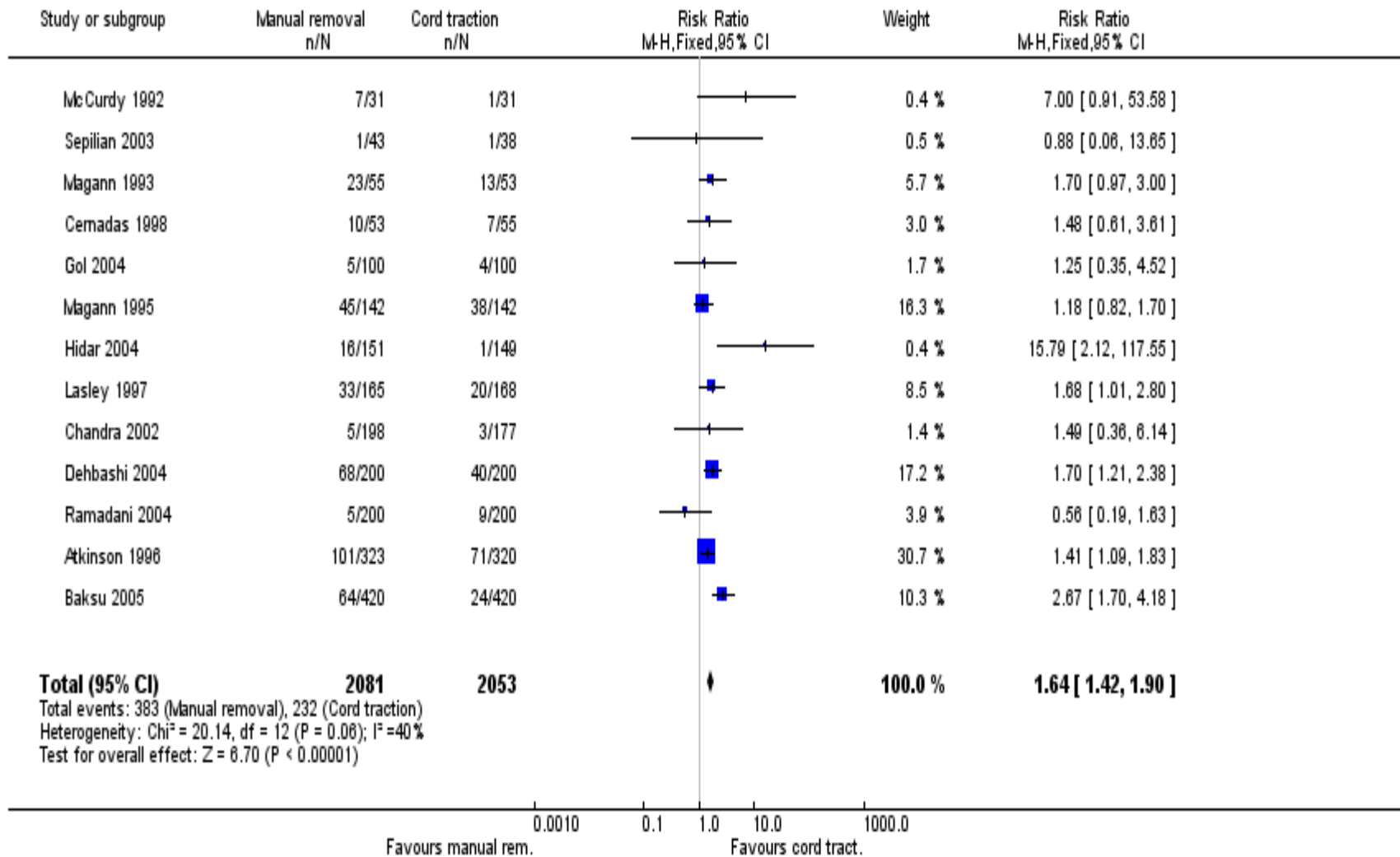
Instrumental delivery of Head

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.. Trials

- ⊗ Cephalic: only one pilot RCT of 44 women.
 - ⊗ No data are available on instrumental delivery of the aftercoming head at CD.
-
- .. the principle of primum non nocere (first do no harm) should be applied in this setting
 - ⊗ Manual delivery of the fetal head should be practiced until further data are available

Review: Methods of delivering the placenta at caesarean section
 Comparison: 1 Manual placental removal versus cord traction
 Outcome: 1 Endometritis

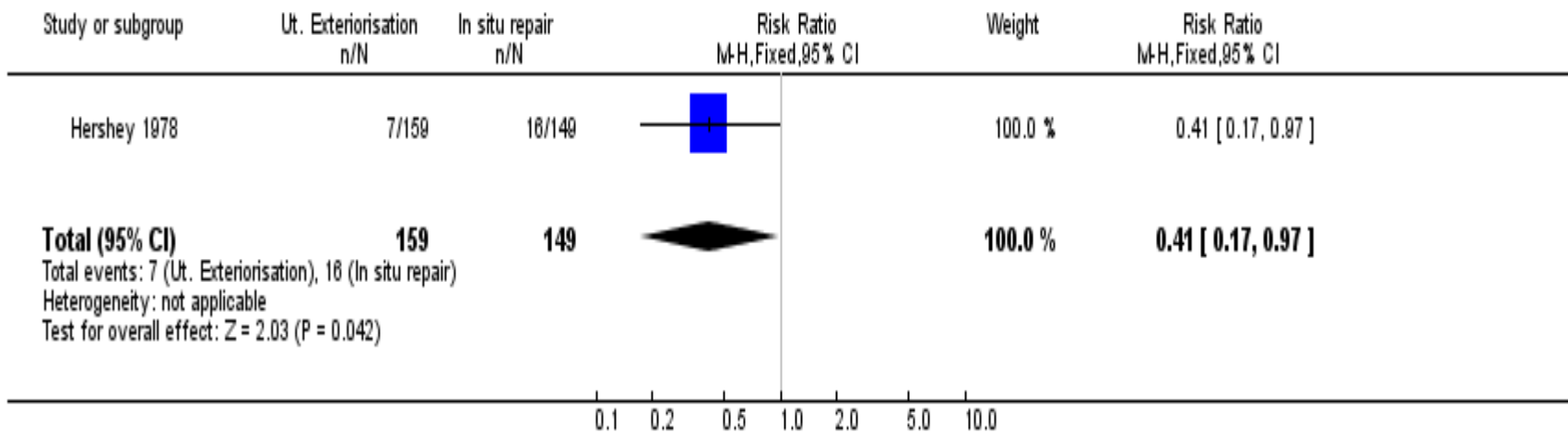


Placental removal

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- .. Manual removal versus Controlled cord traction
 - .. In 13 RCTs including 4134 participants
 - .. Outcome measure: endometritis
- RR: 1.64 (1.42-1.9)
- RD: 7%
- .. A longer interval between birth of the baby and delivery of the placenta is the only disadvantage, but this did not significantly increase the overall duration of surgery.

Review: Extra-abdominal versus intra-abdominal repair of the uterine incision at caesarean section
 Comparison: 1 Uterine exteriorization versus intraperitoneal repair at caesarean section
 Outcome: 4 Febrile morbidity for more than 3 days



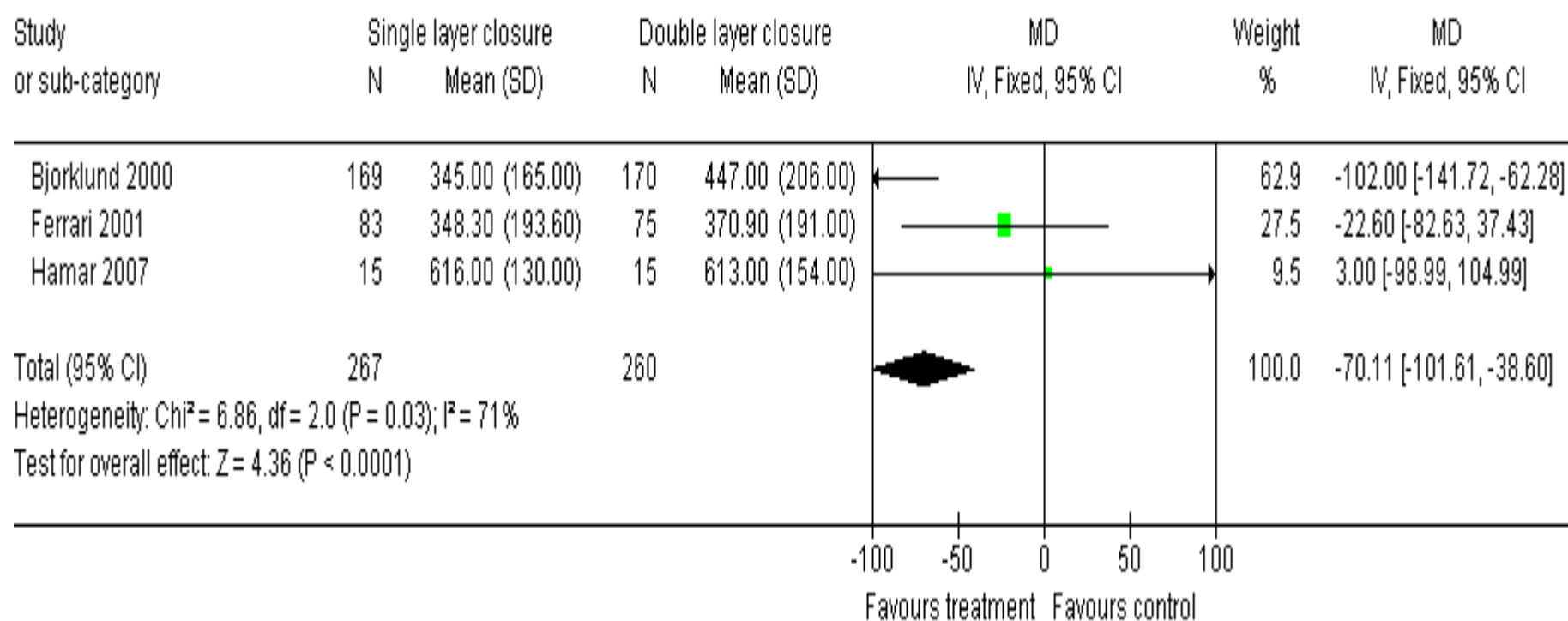
Uterine exteriorization

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- Extra-abdominal vs intra-abdominal repair
- Outcome: Postop fever for >3 days
RR: 0.41 (0.17-0.97)
- Other outcome measures: No difference

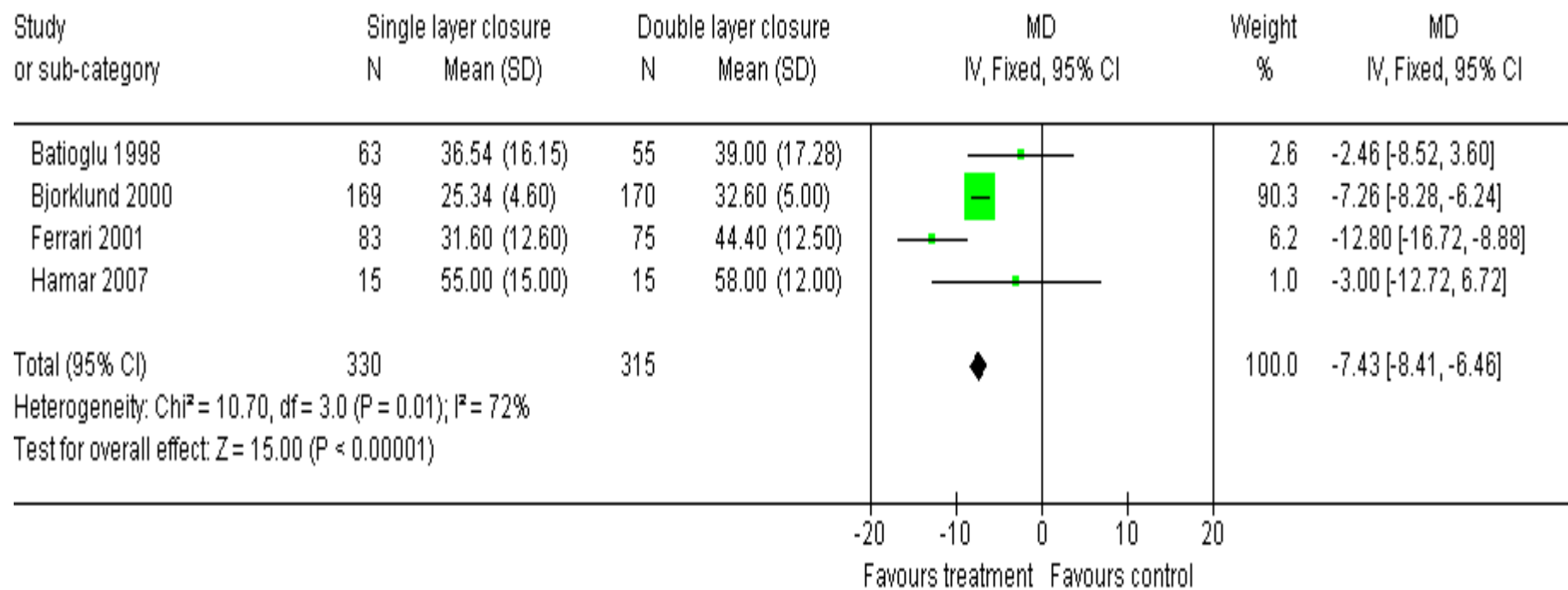
Comparison: 3 Single layer uterine closure versus double layer uterine closure

Outcome: 2 Mean blood loss



Comparison: 3 Single layer uterine closure versus double layer uterine closure

Outcome: 8 Duration of procedure



Closure of the uterine incision

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- .. Single vs 2 layer repair
- .. 2 RCTs involved 1006 women
- .. Single layer repair reduced
 - ⌘ Time
 - ⌘ incidence of abnormal scar (smoother healing)
- .. No evidence for
 - ⌘ dehiscence or uterine rupture (*Knowledge Gap*)

Closure of the uterine incision

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- Experts now recommend the incorporation of all of the muscle up to the serosa in a 1-layer closure to avoid bleeding from edges.

Key messages

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- .. Provide AB prophylaxis
- .. Regional anesthesia
- .. Use JC Incision
- .. Controlled cord traction for placental delivery
- .. Extra abdominal repair of the uterus
- .. Repair the uterus in full thickness
- .. Leave the peritoneum un sutured

THANK YOU

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