

Kangaroo mother care (KMC) for procedural pain in infants: A meta-analysis from the current evidence of randomized control trials and cross-over trials

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ABSTRACT

Background: Kangaroo mother care (KMC), which is also known as Skin-to-skin (STS) care, is supposed to be effective in alleviating the pain of the neonates occurring during various procedures carried out in routine medical care or during the medical examination. **Objectives:** The meta-analysis aimed to determine the effect of the kangaroo mother care method on procedural pain in infants receiving KMC to those receiving only standard care (SC). **Search Strategy:** For this meta-analysis, a systematic literature search was conducted in online database PubMed, Medline, Web of Science, Google Scholar, and the CENTRAL database using MESH terms such as kangaroo mother care method/classification, kangaroo mother care method, kangaroo mother care method/instrumentation, kangaroo mother care method/methods, pain threshold, pain, pain management/methods, pain management/instrumentation, pain management/therapy, and pain management/therapeutic with the help of Boolean terms. **Selection Criteria:** Only randomized control trials or cross-over trials published within ten years and reporting pain assessment during or within five minutes of the pain stimulating procedure assessed using Premature Infant Pain Profile (PIPP) score were considered. **Data Collection and Analysis:** The primary outcome measures were procedural pain assessed by PIPP score and reported in mean and standard deviation along with 95% confidence interval (CI). In cross-over trials, data were taken from the first phase, i.e., before cross-over. **Main Results:** The pooled estimate of the six studies revealed a potential statistically significant benefit of KMC over SC in pain reduction following a pain stimulating procedure ($P = 0.01$, Mean difference = -2.04, 95% CI: -3.65, -0.43, $\text{Chi}^2 = 69.86$, $I^2 = 93\%$). A high level of heterogeneity was found, i.e., 93%. **Conclusion:** Kangaroo mother care seems to be an effective intervention in alleviating the procedural pain due to routine procedures or medication examination.

Keywords: Evidence-based medicine, Infant, Kangaroo-Mother Care method, Pain procedural, Skin-to-skin care

Introduction

Infants during their early phase of life require a repeated number of visits or admission to hospital and medical care for various reasons such as vaccination, venepuncture, cannulation, and even dressing changes and removal of adhesive tapes.^[1] According to

research published by Carbajal *et al.*,^[1] each neonate during their stay in NICU receives an average of 10 pain-inducing procedures, out of which 79% are performed without any specific analgesia. Another study reports this average to be 6.3 procedures per child. During these medical examinations, infants are often subjected to various routine investigations and treatment procedures related to the pain of different intensities. Pain associated with these routine and treatment procedures is referred to as Procedural Pain.^[2-4]

Several Non-pharmacological interventions had been suggested to alleviate this repeatedly occurring procedural pain in health

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care settings; these interventions include kangaroo mother care method, swaddling or facilitated tucking with a blanket, non-nutritive sucking-related strategies such as a pacifier or non-lactating nipples, rocking or holding by the caregiver, therapeutic touch or massage of infant's body, environmental changes like reduction in noise and light intensity, music therapy, stimulated maternal voice, administration of expressed breast milk and video or toy distraction.^[5]

Out of all these, Kangaroo mother care which is a skin-to-skin contact method between a mother and her infant, is considered as one of the essential elements in infants' life. This method, apart from establishing a bond between mother and infant, also helps in improving health-related outcomes like the risk of mortality in infants born weighing less than 2000, risk of hypothermia, duration of hospital stays, nosocomial infections, and risk of severe infections.^[6,7]

Reduction in procedural pain in infants is another of the most important applications of kangaroo mother care. In initial trials and reviews has proved to be an effective intervention in overcoming procedural pain.^[8]

With this objective and updated search, i.e., till November 10, 2020, we tried to assess the effect of the kangaroo mother care method on procedural pain in infants receiving kangaroo mother care to those who receive only standard care.

Methodology

Research question

Effect of kangaroo mother care method on procedural pain in infants receiving kangaroo mother care to those who receive only standard care.

PICO question

Population (P): Infants.

Intervention (I): Infants receiving Kangaroo mother care.

Comparison (C): Infants receiving standard care.

Outcome (O): Reduction in Procedural Pain.

Ethical considerations

This meta-analysis combines narrative synthesis and analysis of a systematic literature search of various previously published randomized control trials and cross-over trials; hence it does not deal with patient-related data collected directly.

Inclusion and Exclusion criteria

Search strategy

A systematic literature search was conducted in online database PubMed, Medline Web of Science, Google Scholar, and the CENTRAL using search string “(“kangaroo mother care method/classification”[MeSH Terms] OR “kangaroo mother care method”[MeSH Terms] OR “kangaroo mother care method/instrumentation”[MeSH Terms] OR “kangaroo mother

care method/methods”[MeSH Terms]) AND (((Kangaroo mother care[Title/Abstract]) OR (Kangaroo care[Title/Abstract])) OR (skin-to-skin contact[Title/Abstract])) AND (((“pain threshold”[MeSH Terms] OR (“pain”[MeSH Terms]) OR (“pain management/methods”[MeSH Terms] OR “pain management/instrumentation”[MeSH Terms] OR “pain management/therapy”[MeSH Terms] OR “pain management/therapeutic use”[MeSH Terms])) AND (((“Pain Relief”[Title/Abstract]) OR (“Pain Control Interventions”[Title/Abstract])) OR (“procedural pain”[Title/Abstract]))” and search filter used were “Publication date-10 years” and “Article type-Randomized Controlled Trial” Similar search terms were used to search Web of Science, Google Scholar, and the CENTRAL database of the Cochrane Library with the help of Boolean terms [Table 1].

Selection criteria

Initial screening was performed by assessors (HS and MR) by reading the title and abstract regarding the eligibility of the studies dealing with the kangaroo mother care method on procedural pain, and only randomized control trials and cross-over trials with human subjects were included. Moreover, those papers that failed to meet the inclusion criteria were excluded. In case of disagreement between the lead researchers regarding the study's inclusion, a third expert was consulted to provide the opinion for inclusion. Following the initial screening, a rigorous literature review was done by assessors (HS and MR) reading full text in pdf and HTML format. Data extraction was carried out based on the desired outcome, i.e., kangaroo mother care method on procedural pain assessed using PPIP score [Figure 1 and Table 1].

Data collection and analysis

The primary outcome measures were procedural pain assessed by PIPP score and reported in mean and standard deviation along with 95% confidence interval (CI). In the case of cross-over trials, data was taken from the first phase, i.e., before cross-over.

Risk of bias assessment

Risk of bias assessment was done using a revised Cochrane risk-of-bias tool for randomized trials “Rob2,” and risk of visualization was done using “Robvis” Tool by Cochrane [Figure 2 and 3].^[9,10]

Results

The initial search using Mesh terms and other relevant keywords identified 18 potentially eligible articles. All these 18 articles were provisionally selected for initial screening. On application of search filters i.e., “Publication date-10 years” and “Article Type-Randomized Controlled Trial”, eight articles were obtained and after initial screening and abstract of these yielded five relevant articles, the full text of the relevant published articles were retrieved using relevant database and those not retrievable were obtained from physical and digital library of All India Institute of Medical Sciences, Raipur Chhattisgarh India

Table 1: Criteria for inclusion and exclusion for publications that were included in the systematic review

Criteria	Inclusion	Exclusion
Period*	≤10 years	>10 years
Language	Any language	-
Article Type	Randomized Controlled Trial (Parallel arm RCTs or cross-over RCTs)	Any other study design and Review articles
The limit regarding the point at which pain was assessed	Assessment of pain during or within 5 min of the event. i.e., pain stimulating procedure	Pain was assessed after 5 min of the event. i.e., pain stimulating procedure
Assessment of procedural pain	Premature Infant Pain Profile (PIPP) score	Pain is assessed by other methods or scales.

*Date of Final Search=10-11-2020

(<http://elibraryiimsraipur.remotexs.in/>). These articles were rigorously reviewed by assessors for inclusion and exclusion criteria and finally, the desired criterion was met by five publications. The study of the bibliography of these five relevant articles yielded additional four articles making nine articles to be included for full text read excluding three studies due to variety of reasons and six studies to be included in the final meta-analysis, which resulted in the conduction of review synthesis as shown [Table 2].

Meta-analysis

To obtain the answer for the PICO question, the pooled estimate was obtained from six studies that reported the mean and standard deviation of procedural pain measured during or immediately after the procedure by Premature Infant Pain Profile (PIPP) score. The pooled estimate of the five studies revealed a potential statistically significant benefit of KMC in comparison to SC in pain reduction following a pain stimulating procedure $P = 0.01$, Mean difference = -2.04, 95% CI: -3.65, -0.43, $\text{Chi}^2 = 69.86$, $I^2 = 93\%$). A high level of heterogeneity was found i.e., 93% [Figure 4].

Since a high level of heterogeneity was obtained i.e., 93%, hence a sensitivity analysis was performed by removing the studies that were showing stronger effect than other studies. The results obtained by sensitivity analysis also revealed a potential statistically significant benefit of KMC in comparison to SC in pain reduction following pain stimulating procedure $P = 0.01$, Mean difference = -0.25, 95% CI: -0.45, -0.05, $\text{Chi}^2 = 0.02$, $I^2 = 0\%$. No heterogeneity was found during the sensitivity analysis i.e., 0% [Figure 5].

Since no heterogeneity was found during the sensitivity analysis hence it was suspected that the heterogeneity was due to the difference in study design hence a separate subgroup analysis was performed to check for the overall estimate. No heterogeneity was obtained within subgroups i.e., 0%, but a very high heterogeneity was obtained i.e., 98.2% between the subgroups [Figure 6].

The pooled estimate of the three studies without heterogeneity revealed a potential statistically significant benefit of KMC in comparison to SC in pain reduction following a pain stimulating procedure $P = 0.06$, Mean difference = -0.25, 95% CI: -0.45, -0.05, $\text{Chi}^2 = 0.02$, $I^2 = 0\%$). No heterogeneity was found i.e., 0% [1.1.1 Studies without heterogeneity, Figure 6].

The pooled estimate of the three studies with heterogeneity also revealed a potential statistically significant benefit of KMC in comparison to SC in pain reduction following a pain stimulating procedure $P = <0.00001$, Mean difference = -3.61, 95% CI: -4.38, -2.84, $\text{Chi}^2 = 1.45$, $I^2 = 0\%$). No heterogeneity was found i.e., 0% [1.1.2 Studies with heterogeneity, Figure 6].

Discussion

Summary and discussion of key findings

In this Meta-analysis on the effect of the Kangaroo mother care method for procedural pain in infants, eight studies were found that met the selection criteria of utilizing the Kangaroo mother care method as an intervention to reduce procedural pain occurring during routine procedures or medical examination. We found out studies related to pain stimulating procedures like heel lance/prick, eye examination, nasal suctioning, and even adhesive tape removal. In this meta-analysis, we included only those studies which assess the outcome of interest i.e., procedural pain by PIPP. In two of the studies, the outcome was not reported properly and in one the outcome was assessed beyond the duration established in inclusion criteria.

The pooled estimate of all the six studies were significantly favouring the Kangaroo mother care method. While three studies showed a stronger effect than the other studies and hence were subjected to sensitivity analysis. The result of the sensitivity analysis also significantly favoured the Kangaroo mother care method in coping up with procedural pain.

The limitation of this meta-analysis includes that we could not determine the main cause of heterogeneity in the overall pooled estimate. We could only assume that the overall heterogeneity was due to a difference in study design or difference in type of procedure imparting the pain of various intensity and difference in KMC care i.e., duration and who provides it.

This systematic review has numerous noteworthy features, including a thorough search with no language restriction and precise inclusion criteria that focused solely on the effect of kangaroo mother care on procedural pain in new-borns getting kangaroo mother care vs those receiving only conventional care. Furthermore, only randomised controlled studies (parallel arm or cross over trials) were included, as they give a high standard evidence for evidence-based practise based on true estimations.

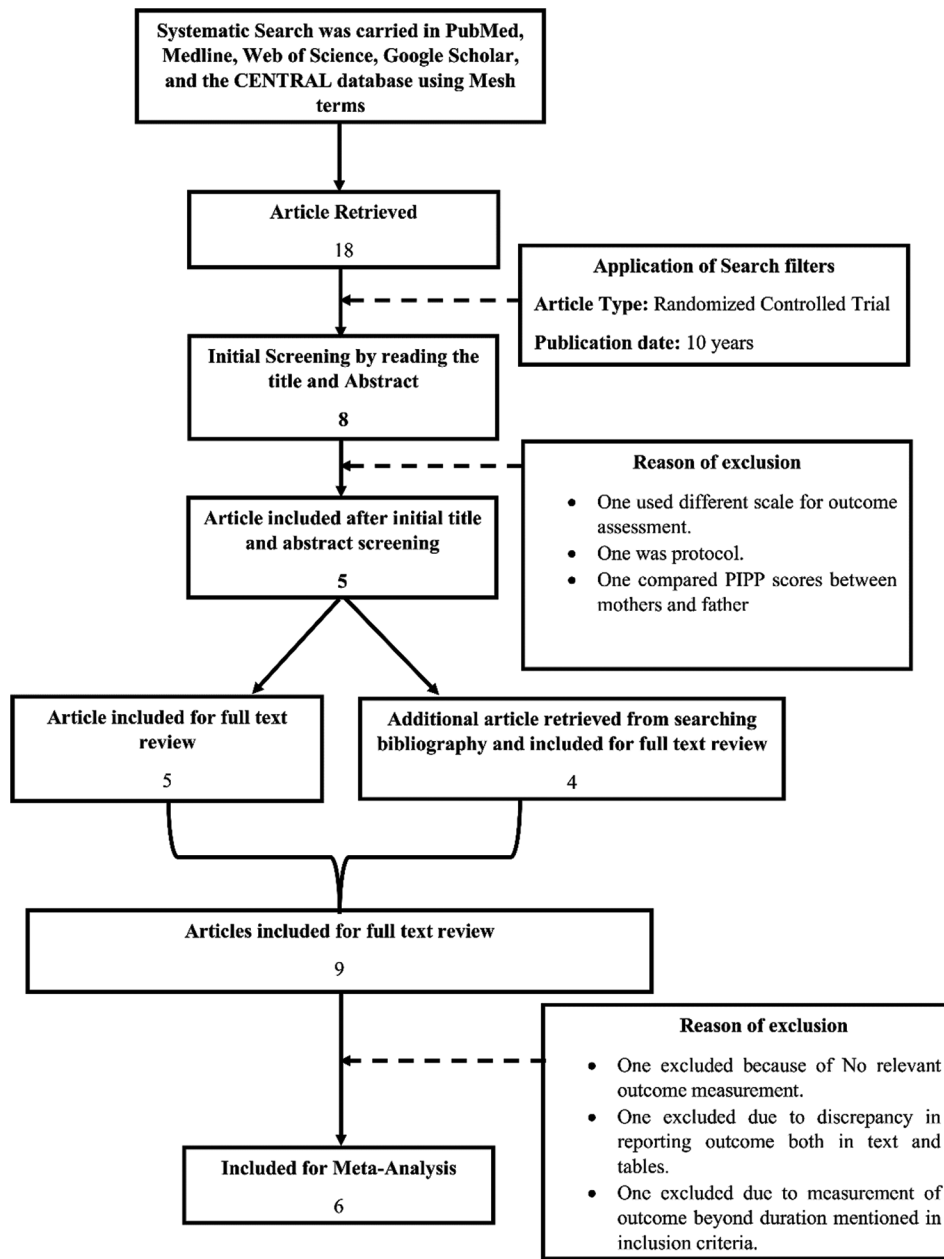


Figure 1: PRISMA flow diagram of studies included in the meta-analysis

Study	Risk of bias domains					Overall
	D1	D2	D3	D4	D5	
Mitchell et al. 2013 ^[17]	⊗	⊖	⊕	⊗	⊕	⊗
Nanavati et al. 2013 ^[18]	⊕	⊕	⊕	⊕	⊕	⊕
Nimbalkar et al. 2013 ^[19]	⊕	⊕	⊕	⊕	⊕	⊕
Mosayebi et al. 2014 ^[20]	⊕	⊖	⊕	⊕	⊕	⊕
Shukla et al. 2018 ^[21]	⊕	⊕	⊕	⊕	⊕	⊕
Kristoffersen et al. 2019 ^[22]	⊖	⊕	⊕	⊕	⊕	⊖

Domains:
D1: Bias arising from the randomization process.
D2: Bias due to deviations from intended intervention.
D3: Bias due to missing outcome data.
D4: Bias in measurement of the outcome.
D5: Bias in selection of the reported result.

Judgement
⊗ High
⊖ Some concerns
⊕ Low

Figure 2: Risk of bias assessment by revised Cochrane risk-of-bias tool for randomized trials "Rob2" and risk of visualization by "Robvis" Tool by Cochrane

This meta-analysis shows that kangaroo mother care not only helps to minimize mortality in infants, but it can also help to lessen infant pain in medical settings, regardless of whether the mother or father delivered the KMC or STS care, as evidenced by a recent trial published in 2021 by Shukla *et al.*, which every general primary care provider and family physician should be aware of.^[17,18]

A similar meta-analysis published by Cochrane in 2017 and by Boundy *et al.*^[19] in 2016, also shows a similar outcome. With pooled analysis of various RCTs significantly favours skin-to-skin care (SSC) over standard care in reducing the pain.^[8]

Table 2: Studies included in the meta-analysis

Author and year	Study Design	Sample Size	Aim of the study	Pain producing procedure	Duration and time of intervention	The method used for assessment	Outcomes of Interest
Mitchell <i>et al.</i> 2013 ^[11]	Randomized Controlled Trial	38 preterm infants (27-30 weeks gestational age), 28 in KC intervention, 26 in SC intervention	To determine whether KC provides sustainable pain relief beyond the period of STS holding.	Nasal suctioning	2 h daily, time of delivery of intervention unknown	PIPP Score	KC (7.64±0.40) SC (7.89±0.21)
Nanavati <i>et al.</i> 2013 ^[12]	Randomized Controlled Trial	50 VLBW neonates, 25 divided equally into KMC and EBM groups.	To compare the pain relief effect of KMC and EBM on the pain associated with adhesive tape removal in VLBW neonates.	Adhesive Tape Removal	15 min before procedure till end of the procedure	PIPP Score	KMC (5.92±1.89) EBM (6.20±2.10)
Nimbalkar <i>et al.</i> 2013 ^[13]	Randomized controlled double-masked cross-over trial	50 neonates, between (32-36 weeks 6 d gestational age), and weighing <2500 g, 21 to KMC group and 29 to non-KMC group	To determine the effect of KMC of the small duration of 15 min in decreasing pain in preterm neonates between 32-36 weeks 6 d on heel prick by a 26-gauge needle.	Heel Prick	15 min before, during, and 15 min after the procedure	PIPP Score	KMC (5.38±3.25) Non-KMC (10.23±4.59)
Mosayebi <i>et al.</i> 2014 ^[14]	Single-blind cross-over randomized clinical trial	Sixty-four vitally stable premature newborns were divided equally into Incubator and KMC groups.	This study aimed to assess the effect of KMC for a brief duration of 15 minutes on pain intensity of heel lance in preterm newborns admitted to neonatal intensive care units.	Heel Lance/ Prick	15 min before, during, and 2 min after the procedure	PIPP Score	KMC (5.81±2.69) Incubator (9.12±3.02)
Shukla <i>et al.</i> 2018 ^[15]	Randomized Controlled Trial	Two hundred neonates (26-36-week gestational age) KMC with MT group, MT group, KMC group or Control (no additional intervention) group with 50 neonates in each.	To compare the efficacy of two pain control interventions and interaction effects (if any).	Heel Prick	10 min before the unknown duration	PIPP Score	KMC (7.7±3.9) Control (11.5±3.4)
Kristoffersen <i>et al.</i> 2019 ^[16]	Randomized cross-over design	Thirty-five preterm infants (<32 weeks of gestational age), 21 in the STS group and 25 in the SC group.	The pain-relieving effect of STS contact versus SC in the incubator during screening for retinopathy of prematurity.	Eye Examination for screening of retinopathy	30 min before and during the procedure	PIPP Score	STS (7.0±3.4) SC (6.8±2.6)

KMC - Kangaroo mother care, KC - Kangaroo care, SC - Standard care, STS - Skin-to-skin, Min - Minutes, MT - Music therapy, PIPP - Premature Infant Pain Profile score, VLBW - Very Low Birth Weight, EBM - Expressed Breast Milk

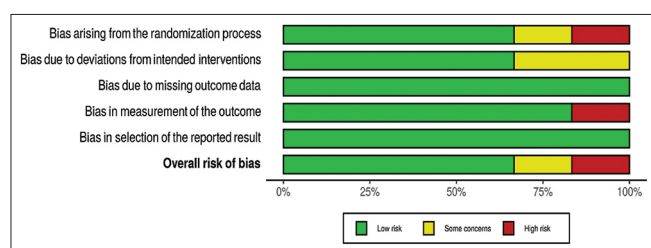


Figure 3: Risk of bias assessment summary table by Risk of visualization "Robvis" Tool by Cochrane

Interpretation and implications

Within the limitations of this systematic review and meta-analysis and from the quality of evidence obtained from the available RCTs and cross-over trails, Kangaroo mother care seems to be effective in alleviating the procedural pain which occurs due to routine procedures or during medical examinations. Hence all the mothers in Neonatal Intensive Care Units (NICUs) should be encouraged to practice kangaroo mother care which may also benefit to alleviate the pain of their infant during various routine

procedures apart from other multiple benefits like improved bond with infant, increased breast milk production/supply and decrease mortality in low-birth-weight infant.

Key take home messages

- KMC, also known as STS care, is helpful not only in reducing neonatal mortality, but also in reducing procedural pain that occurs during routine procedures or during necessary medical examinations.
- KMC, also known as STS care, is helpful in reducing procedural pain regardless of whether the mother or father delivered the KMC or STS care.

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Conflicts of interest

There are no conflicts of interest.

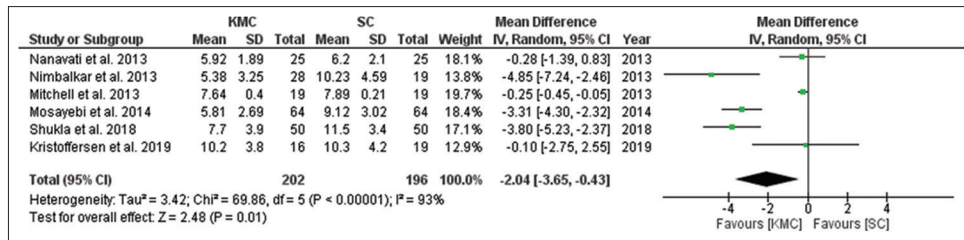


Figure 4: Pooled analysis of all the studies

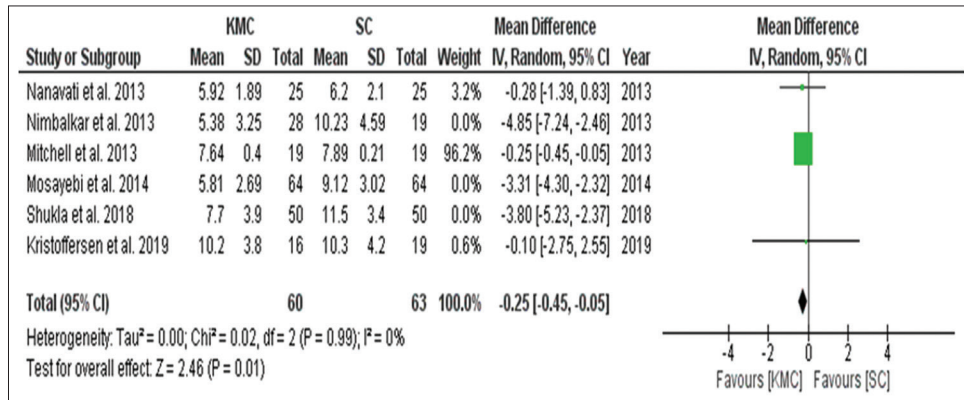


Figure 5: Sensitivity analysis of all the studies

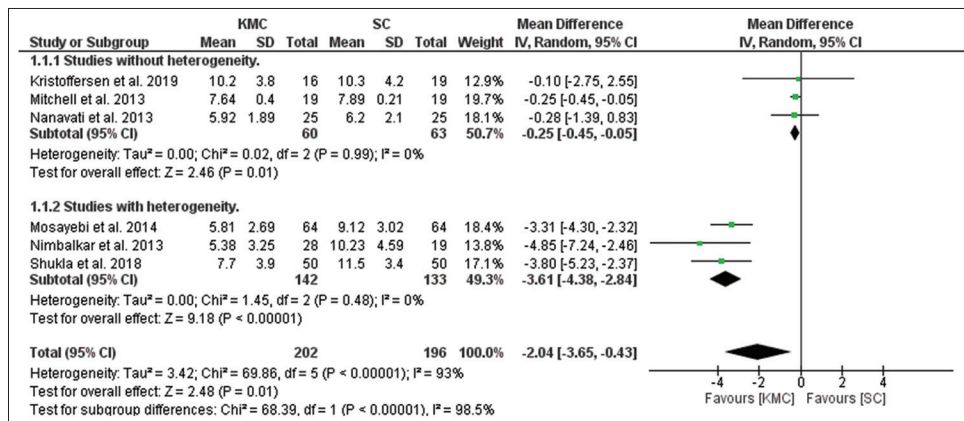


Figure 6: Subgroup analysis of all the studies

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