<table>
<thead>
<tr>
<th>Reference</th>
<th>Methods</th>
<th>Details</th>
<th>Dosing regimen</th>
<th>Outcomes</th>
<th>Efficacy Results</th>
<th>Remedication, exclusions, and adverse events</th>
<th>Safety results</th>
<th>Quality score</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Berti et al.</strong> A prospective, randomised comparison of dexketoprofen, ketoprofen, or paracetamol for postoperative analgesia after outpatient knee arthroscopy. Minerva Anestesiologica 2000; 66:549-554</td>
<td>RCT, double oral dose, parallel groups, LA</td>
<td>Knee arthroscopy</td>
<td>Dexketoprofen 25mg BID N= 15</td>
<td>Pain Intensity (at rest) 100mm VAS</td>
<td>Mean VAS on movement significantly higher with paracetamol than other patients. Maximum pain moderate or severe in first 24 hours, 3 dexketoprofen, 6 ketoprofen, 5 paracetamol</td>
<td>No patients remedicated during their hospital stay, 2 patients remedicated following discharge, no info on missing data handled</td>
<td>No adverse events were reported</td>
<td>R 2 DB 0 WD 1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Assessed during first 24 hrs and by telephone interview the following day - no further info??</td>
<td>Ketoprofen 50mg BID N= 15</td>
<td>Pain Intensity (during motion) 100mm VAS</td>
<td></td>
<td></td>
<td></td>
<td>Total = 3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Paracetamol 500mg BID N= 15</td>
<td>Pain 5-pt VRS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>OPVS = 3/16</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Medication administered before nerve block placement and every 6/8 hrs thereafter</td>
<td>Quality of care</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>N= 45</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>N= 15</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td></td>
<td>N= 15</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Ioham et al.</strong> Effect of perioperative administration of dexketoprofen on opioid requirements and inflammatory response following elective hip arthroplasty. Br J Anaesth 2002; 88: 520-526</td>
<td>RCT, DB, 3 oral doses for three days, parallel groups, LA</td>
<td>Hip arthroscopy</td>
<td>Dexketoprofen 25mg TID N= 15</td>
<td>Pain VAS</td>
<td>Dexketoprofen 25mg TID Cumulative morphine consumption 0.85mg Time to first analgesia 1277 ± 1031 mins</td>
<td>No adverse events attributable to dexketoprofen were reported, does not provide any information about unrelated adverse events - may not have been collected</td>
<td>Withdrawals not reported</td>
<td>R 1 DB 1 WD 0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Assessed at 24 and 18 hrs preoperatively, 6, 24, and 48 hrs postoperatively</td>
<td>Placebo N= 15</td>
<td>Cumulative opioid consumption</td>
<td></td>
<td></td>
<td></td>
<td>Total = 2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Medication administered 25mg three times daily for 24hrs before and 48hrs after surgery. Following recovery all patients access to a PCA system with morphine</td>
<td>Adverse events associated with opioid administration (nausea, respiratory depression, pruritus, sedation, urinary retention)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>OPVS = 13/16</td>
</tr>
<tr>
<td></td>
<td></td>
<td>N= 30</td>
<td>3/4-pt ordinal scales</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Zapata et al.</strong> Dexketoprofen vs tramadol: randomized double-blind trial in patients with postoperative pain. British J Clin Pharmacol 2000: 223 (abs 870). Data from Harrison F: Double-blind randomised, parallel-group comparison of the safety and efficacy of oral dexketoprofen 25 mg with tramadol 50 mg in subjects with moderate to severe pain following orthopaedic surgery. Clinical Trial Report 2001.</td>
<td>RCT, DB, 8 oral doses, parallel groups</td>
<td>Orthopaedic surgery</td>
<td>Dexketoprofen tramadol trometamol 25mg, N= 93</td>
<td>Pain Intensity 100mm VAS</td>
<td>Desksetoprofen tramadol 25mg SPID6 13.9 ± 11.6 TOTPAR6 16.1 ± 5.4 Global good/excellent Time to onset 3 ± 1</td>
<td>49 patients reported 69 adverse events; there were no serious adverse events and most were mild to moderate in severity</td>
<td>Withdrawals not reported</td>
<td>R 2 DB 1 WD 1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>17 centres in Germany, Belgium, and the Netherlands</td>
<td>Pain Intensity 4-pt VRS (0 - none, 1 - mild, 2 - moderate, 3 - severe)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Total = 4</td>
</tr>
<tr>
<td></td>
<td></td>
<td>N= 187</td>
<td>Pain Relief 5-pt VRS (0 - no relief, 1 - little, 2 - moderate, 3 - significant, 4 - complete)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>OPVS = 10/16</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Orthopaedic surgery</td>
<td>Global efficacy (patient) 4-pt VRS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>N= 187</td>
<td>Global efficacy (investigator) 4-pt VRS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

RCT, DB, three oral doses, parallel groups, GA
Assessed at baseline, 15, 30 and 45 mins, and 1, 2, 3, 4, 5 and 6 hrs during the single dose phase, patients were assessed at the end of treatment (24 hrs) for the multiple dose phase
Medication administered once pain was rated as at least 'moderate'. 2nd and 3rd doses were given 8 and 16 hrs later

Hallux valgus (bunion) surgery

Ketoprofen 50mg TID
N=55
Placebo
N=47

Dexketoprofen trometamol 25mg TID
N=52

Dexketoprofen trometamol 12.5mg TID
N=47

Data of patients remedicating after the 1st hr were withdrawn, patients remedicating after the 1st hr LOCF for intent to treat analysis

Patients remedicating during the 1st hr were withdrawn, patients remedicating after the 1st hr LOCF for intent to treat analysis

Schreiber M. Double-blind, randomized, parallel-group comparison of the safety and efficacy of oral doses of dexketoprofen trometamol salt (LM-1158.TRIS, 12.5 mg or 25 mg) with nimesulide ketoprofen (50 mg) and placebo in patients with moderate or severe pain following orthopaedic surgery. Clinical Trial report, 1996.

RCT, DB, three oral doses for three days, parallel groups, LA or GA, 12 hr analgesic washout
Assessed at baseline, 30 mins, and 1, 2, 3, 4, 5 and 6 hrs after the 1st dose and baseline, 1 and 2 hrs after doses 2 to 9
Medication administered when pain described as moderate or severe within 4 hrs of surgery

Knee (meniscectomy or ligament reconstruction) or ankle surgery

Ketoprofen 50mg TID
N=52

Dexketoprofen trometamol 25mg TID
N=52

Dexketoprofen trometamol 12.5mg TID
N=52

Dexketoprofen 25mg TID
N=52

Placebo
N=55

Ketoprofen 50mg TID versus ketoprofen (50 mg tid) and placebo after oral administration in patients with acute post-surgery pain. Clinical Trial report, 1999.

Pain Intensity
100mm VAS

Global efficacy (investigator)
4-pt VRS (not effective, mediocre, good, excellent)

Global efficacy (patient)
4-pt VRS (excellent, good, mediocre, null)

R2

SPID6
347.3 ± 556.1

TOTPAR6
2.7 ± 10.3

Time to remedication
138.7 ± 97.3

Morphine usage
9.2 ± 6.2

Dexketoprofen trometamol 12.5mg TID

SPID6 77.8 ± 525.9

TOTPAR6 7.4 ± 17.4

Time to remedication 131.7 ± 92.2

Morphine usage 9.9 ± 6.7

Placebo

SPID6 347.3 ± 556.1

TOTPAR6 2.7 ± 10.3

Global good/excellent 27

Time to min pain intensity 24.7 ± 38.4

Morphine usage 8.2 ± 5.1

Dexketoprofen 25mg TID

SPID6 126.1 ± 485

TOTPAR6 7.4 ± 17.4

Global good/excellent 28

Time to min pain intensity 43.9 ± 71

Morphine usage 9.0 ± 6.2

Ketoprofen 50mg TID

SPID6 280.8 ± 567.8

TOTPAR6 2.7 ± 10.3

Global good/excellent 25

Time to min pain intensity 21.6 ± 48.1

Morphine usage 9.9 ± 6.7

In total 112 patients reported 166 adverse events; there were significantly more patients experiencing adverse events; more placebo and dex 12.5mg reported at least one adverse event than dex 25mg

No with >1 AE 0

Placebo

No with >1 AE 3

All cause withdrawals 3

AE withdrawals

No with >1 AE 4

All cause withdrawals 5

AE withdrawals

No with >1 AE 3

All cause withdrawals 3

AE withdrawals 2

No with >1 AE 3

All cause withdrawals 3

AE withdrawals

No with >1 AE 0

All cause withdrawals 3

AE withdrawals 0

No with >1 AE 3

All cause withdrawals 0

AE withdrawals 0

No with >1 AE 0

All cause withdrawals 3

AE withdrawals 3

No with >1 AE 0

All cause withdrawals 2

No with >1 AE 3

All cause withdrawals 3

AE withdrawals
Perez et al. A multicentre clinical trial evaluating the analgesic efficacy and safety of dexketoprofen trometamol (25 mg tid) versus diclofenac (50 mg tid) for the treatment of pain subsequent to ambulatory surgery. Clinical trial report 2002

RCT, DB, three oral doses for three days, parallel groups, LA or GA, 12 hr analgesic washout. Assessed at baseline and after two hrs for each dose. Medication administered when the patient met all the discharge criteria or reported pain, mild pain included in the description of baseline demographics.

Inguinal or rural herniorrhaphy
N=173
7 centres in Spain

Dexketoprofen trometamol 25mg TID
N=83

Diclofenac 50mg TID
N=80

Pain Intensity
100mm VAS

Diclofenac 50mg TID at 4th and 8th doses, though no difference for pain relief

Assessed at baseline and after two hrs for each dose.

Global efficacy (patient)
4-pt VRS (excellent, good, mediocre, null)

Quality of sleep
Pain Intensity 100mm VAS
Rescue analgesics

Pain relief
5-pt VRS (0 - no relief, 1 - slight relief, 2 - moderate relief, 3 - considerable relief, 4 - complete relief)

Diclofenac 50mg TID at 4th and 8th doses, though no difference for pain relief

R 2
DB 2
WD 1
Total = 5
OPVS = 13/16

Schreiber M. Comparison of efficacy and tolerability of oral administration of 25 mg dexketoprofen trometamol vs 50 mg tramadol in patients with post-operative pain. Clinical trial report 1998

RCT, DB, parallel groups, 24 hr analgesic washout. Pan intensity 40/100 mm at baseline.

Arthroscopy and other out-patient surgical procedures
14 centres in Germany

Dexketoprofen trometamol 25mg
N=93
38 included in ITT because of protocol violations

Tramadol 50mg
N=91
43 included in ITT because of protocol violations

Pain Intensity
100mm VAS

No significant difference in pain intensity in a number of different analyses, nor in rescue medication used.

Quality of sleep
Pain Intensity 100mm VAS
Rescue analgesics

No significant difference in morphine consumption or pain

A total of 76 patients reported 117 adverse events, there were no statistically significant differences between groups. 1 serious adverse event was reported.

R 2
DB 2
WD 1
Total = 5
OPVS = 13/16


R, DB, parallel groups, 3 daily doses over 3 days, GA. Assessed at baseline, 4, 12, 20, 28, 36, 44, and 52 hrs.

Hip replacement 25 anesthesiological teams in France
PCA morphine was also available

Dexketoprofen trometamol 25mg TID ± self-administered morphine
N= 100

Paracetamol 500mg ± codeine 22.5mg TID ± self-administered morphine
N= 100

Pain intensity
11-pt VRS

No significant difference in morphine consumption or pain

Global efficacy (physician)
4-pt VRS (good, relatively good, little satisfactory, poor)

Sedation

No difference in adverse events

R 2
DB 2
WD 1
Total = 5
OPVS = 13/16


R, DB, parallel groups, oral dexketoprofen 25 mg 1 hour before and 8-16 hours after surgery. Tramadol consumption from PCA

Abdominal hysterectomy Turkey

Dexketoprofen 25 mg 1 hour before and 8-16 hours after surgery

Tramadol consumption through PCA

Phasebo

Significantly less tramadol used by patients with dexketoprofen, and lower pain scores

Significantly less tramadol used by patients with dexketoprofen, and lower pain scores

No difference in adverse events

R 1
DB 0
WD 0
Total = 1
OPVS = 7/16


R, DB, parallel groups, 3 daily doses over 3 days, GA. Assessed at baseline, 4, 12, 20, 28, 36, 44, and 52 hrs.

Hip replacement 25 anesthesiological teams in France
PCA morphine was also available

Dexketoprofen trometamol 25mg TID ± self-administered morphine
N= 100

Paracetamol 500mg ± codeine 22.5mg TID ± self-administered morphine
N= 100

Pain intensity
11-pt VRS

No significant difference in morphine consumption or pain

Global efficacy (physician)
4-pt VRS (good, relatively good, little satisfactory, poor)

Sedation

No difference in adverse events

R 2
DB 2
WD 1
Total = 5
OPVS = 13/16


R, DB, parallel groups, oral dexketoprofen 25 mg 1 hour before and 8-16 hours after surgery. Tramadol consumption from PCA

Abdominal hysterectomy Turkey

Dexketoprofen 25 mg 1 hour before and 8-16 hours after surgery

Tramadol consumption through PCA

Phasebo

Significantly less tramadol used by patients with dexketoprofen, and lower pain scores

Significantly less tramadol used by patients with dexketoprofen, and lower pain scores

No difference in adverse events

R 1
DB 0
WD 0
Total = 1
OPVS = 7/16
### Intramuscular and intravenous administration


<table>
<thead>
<tr>
<th>Orthopaedic surgery</th>
<th>Dexketoprofen trometamol 50mg IM BID ± morphine</th>
<th>Dexketoprofen trometamol 50mg IM BID</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=172</td>
<td>Time to loading morphine dose</td>
<td>Time to loading dose 36mins</td>
<td></td>
</tr>
<tr>
<td>15 centres in the UK</td>
<td>Time to first use of PCA morphine</td>
<td>Time to PCA 78</td>
<td></td>
</tr>
<tr>
<td>Pain Intensity</td>
<td>10mm VAS</td>
<td>Pain Intensity</td>
<td></td>
</tr>
<tr>
<td>5 pt VRS (0 - none, 1 - mild, 2 - moderate, 3 - severe)</td>
<td>4-pt VRS (0 - none, 1 - mild, 2 - moderate, 3 - severe)</td>
<td>4-pt VRS (0 - none, 1 - mild, 2 - moderate, 3 - severe)</td>
<td>Pain Intensity</td>
</tr>
<tr>
<td>Quality of sleep</td>
<td>5 pt VRS (excellent, good, minor discomfort, major discomfort, hardly slept at all)</td>
<td>Sedation scoring</td>
<td>Sedation scoring</td>
</tr>
<tr>
<td>4-pt VRS (0 - fully awake, 1 - mildly sedated, 2 - heavily sedated, 3 - fully awake)</td>
<td>4-pt VRS (0 - fully awake, 1 - mildly sedated, 2 - heavily sedated, 3 - fully awake)</td>
<td>4-pt VRS (0 - fully awake, 1 - mildly sedated, 2 - heavily sedated, 3 - fully awake)</td>
<td>4-pt VRS (0 - fully awake, 1 - mildly sedated, 2 - heavily sedated, 3 - fully awake)</td>
</tr>
<tr>
<td>Total cumulative amount of morphine used</td>
<td>Total cumulative amount of morphine used</td>
<td>Total cumulative amount of morphine used</td>
<td>Total cumulative amount of morphine used</td>
</tr>
<tr>
<td>39.1mg ± 16.5mg</td>
<td>21.2mg ± 16.3mg</td>
<td>15.8mg ± 16.0mg</td>
<td>13.6mg ± 15.6mg</td>
</tr>
<tr>
<td>Time to remedication</td>
<td>4.28 ± 8.1 hrs</td>
<td>4.28 ± 8.1 hrs</td>
<td>4.28 ± 8.1 hrs</td>
</tr>
<tr>
<td>No remedicating</td>
<td>91</td>
<td>95</td>
<td>95</td>
</tr>
<tr>
<td>All cause withdrawals</td>
<td>132</td>
<td>139</td>
<td>139</td>
</tr>
<tr>
<td>Total</td>
<td>3</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>OPVS</td>
<td>10/16</td>
<td>13/16</td>
<td>13/16</td>
</tr>
</tbody>
</table>
| **Remedication permitted, patients remedicating within the first 30 mins were withdrawn. Missing VAS scores due to patient sleeping were inputted as 0, LOCF used for patients withdrawing after first 30 min due to adverse events or missing more than one VAS score. 5 patients were excluded from the ITT analysis, all due to missing baseline or post-baseline measurements. 132 patients reported 223 adverse events, 208 patients withdrew as a result of adverse events.**


<table>
<thead>
<tr>
<th>Orthopaedic surgery</th>
<th>Ketoprofen 100mg IM TID</th>
<th>Ketoprofen 100mg IM TID</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=252</td>
<td>Time to loading dose 36mins</td>
<td>Time to PCA 78</td>
<td></td>
</tr>
<tr>
<td>11 centres in Belgium, France, Germany and South Africa</td>
<td>Time to loading dose 36mins</td>
<td>Time to PCA 78</td>
<td></td>
</tr>
<tr>
<td>Pain Intensity</td>
<td>10mm VAS</td>
<td>Pain Intensity</td>
<td></td>
</tr>
<tr>
<td>4-pt VRS (0 - none, 1 - mild, 2 - moderate, 3 - severe)</td>
<td>4-pt VRS (0 - none, 1 - mild, 2 - moderate, 3 - severe)</td>
<td>4-pt VRS (0 - none, 1 - mild, 2 - moderate, 3 - severe)</td>
<td>Pain Intensity</td>
</tr>
<tr>
<td>Quality of sleep</td>
<td>5 pt VRS (excellent, good, minor discomfort, major discomfort, hardly slept at all)</td>
<td>Sedation scoring</td>
<td>Sedation scoring</td>
</tr>
<tr>
<td>4-pt VRS (0 - fully awake, 1 - mildly sedated, 2 - heavily sedated, 3 - fully awake)</td>
<td>4-pt VRS (0 - fully awake, 1 - mildly sedated, 2 - heavily sedated, 3 - fully awake)</td>
<td>4-pt VRS (0 - fully awake, 1 - mildly sedated, 2 - heavily sedated, 3 - fully awake)</td>
<td>4-pt VRS (0 - fully awake, 1 - mildly sedated, 2 - heavily sedated, 3 - fully awake)</td>
</tr>
<tr>
<td>Total cumulative amount of morphine used</td>
<td>Total cumulative amount of morphine used</td>
<td>Total cumulative amount of morphine used</td>
<td>Total cumulative amount of morphine used</td>
</tr>
<tr>
<td>64.8mg ± 6.1mg</td>
<td>50mg ± 5.8mg</td>
<td>41.3mg ± 5.3mg</td>
<td>41.3mg ± 5.3mg</td>
</tr>
<tr>
<td>Time to remedication</td>
<td>4.28 ± 8.1 hrs</td>
<td>4.28 ± 8.1 hrs</td>
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<tr>
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<td>91</td>
<td>95</td>
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<td>All cause withdrawals</td>
<td>132</td>
<td>139</td>
<td>139</td>
</tr>
<tr>
<td>Total</td>
<td>3</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>OPVS</td>
<td>10/16</td>
<td>13/16</td>
<td>13/16</td>
</tr>
</tbody>
</table>

**Remedication permitted, patients remedicating within the first 30 mins were withdrawn. Missing VAS scores due to patient sleeping were inputted as 0, LOCF used for patients withdrawing after first 30 min due to adverse events or missing more than one VAS score. 5 patients were excluded from the ITT analysis, all due to missing baseline or post-baseline measurements. 132 patients reported 223 adverse events, 208 patients withdrew as a result of adverse events.**
Peatt S. Double blind, randomised, parallel group study of the safety, efficacy and influence on morphine usage of intravenous dexketoprofen trometamol (50 mg) in comparison to intravenous tramadol (100 mg) or placebo in the relief of pain following orthopaedic surgery. Clinica trial report 2000

RCT, DB, DD, double dose, parallel groups, GA, 6hr analgesic washout
Assessed at 30 mins and 1, 2, 3, 4, 6, 10 and 12 hrs
Medication administered approx 30 mins before anticipated waking time and the second dose 6hrs later. All patients were connected to a PCA system with IV morphine and received a loading dose if required

Orthopaedic surgery (hip or knee replacement) 18 centres in Belgium, the Netherland, South Africa and the UK
N= 215

Dexketoprofen 50mg IV BID N= 73
Tramadol 100mg IV BID N= 73
Placebo N= 69

Pain Intensity
100mm VAS

Hourly rate of morphine usage
Time to first PCA demand
Pain scores and morphine requirements similar in both active groups, and both significantly better than placebo

Dexketoprofen 50mg IV BID
SPID6 175.5
SPID12 269.8
Mean morphine consumption 20.1 ± 12
Hourly morphine consumption 1.7 ± 0.7
Time to first PCA use 72.6 ± 56.2
No of PCA demands 3.68 ± 4.5

Tramadol 100mg IV BID
SPID6 204.6
SPID12 306.1
Mean morphine consumption 19.6 ± 10.2
Hourly morphine consumption 1.6 ± 0.8
Time to first PCA use 68.4 ± 4.9
No of PCA demands 3.64 ± 4.5

Placebo
SPID6 220.7
SPID12 367.9
Mean morphine consumption 26.8 ± 12.2
Hourly morphine consumption 2.2 ± 1
Time to first PCA use 57.6 ± 28.9
No of PCA demands 4.42 ± 3.8

For patients withdrawing due to adverse events or therapeutic efficacy LOCF used, for patients withdrawing due to lack of efficacy, the maximum VAS score from baseline to the last measurement was carried forward

7 patients were excluded as the PCA morphine was not set up and 4 patients did not receive two doses of study medication

104 patients reported 179 adverse events, 4 patients experienced serious adverse events (1 dexketoprofen patient and 3 tramadol patients) - 2 of which died for reasons unrelated to the study drugs

Dexketoprofen 50mg IV BID
No with >1 AE 37
All cause withdrawals 2
AE withdrawals 1

Tramadol 100mg IV BID
No with >1 AE 35
All cause withdrawals 4
AE withdrawals 1

Placebo
No with >1 AE 32
All cause withdrawals 2
AE withdrawals 1

7 patients were excluded as the PCA morphine was not set up and 4 patients did not receive two doses of study medication
Puig et al. Multicentre clinical trial to assess the efficacy and safety of dexketoprofen trometamol (25 mg and 50 mg bid) versus diclofenac (75 mg bid) by the intramuscular route in the treatment of postoperative pain. Clinical trial report 2000

RCT, DB, double IM dose, parallel groups

Assessed at baseline, 15, 30 and 45 mins, and 1, 1.5, 2, 3, 4, 5, 6, and 8 hrs

Medication administered when pain >30mm within 12 hrs of surgery

Abdominal gynaecological (non laparoscopic) surgery

22 centres in Spain, Denmark and Sweden

N= 340

Dexketoprofen trometamol 25mg IM BID

N= 74

Dexketoprofen trometamol 50mg IM BID

N= 71

Diclofenac 75mg IM BID

N= 68

Placebo

N= 71

Pain Intensity

100mm VAS

Pain relief

5 pt VRS (0 - no pain to 4 - complete relief)

Morphine consumption

Overall assessment of efficacy

Quality of sleep

Sedation

4 pt VRS (0 - awake to 3 - asleep)

Dexketoprofen trometamol 25mg IM BID

SPID6 3.3 ± 4.1

TOTPAR6 9.1 ± 7.3

TOTPAR6 10.8 ± 7.6

Time to max PID 60 (30 - 120)

No remedicating (1st dose) 51

Morphine consumption (1st dose) 5.5 ± 7.8

Dexketoprofen trometamol 50mg IM BID

SPID6 5.2 ± 8.7

TOTPAR6 12.7 ± 8.2

TOTPAR6 16 ± 11.1

Time to max PID 60 (30 - 120)

No remedicating (1st dose) 32

Morphine consumption (1st dose) 3.3 ± 6.5

Diclofenac 75mg IM BID

SPID6 4.3 ± 4.5

SPID6 5.8 ± 8.1

TOTPAR6 11.4 ± 8.4

TOTPAR6 14.5 ± 11.4

Time to max PID 60 (30 - 240)

No remedicating (1st dose) 36

Placebo SPID6 1.4 ± 4.2

TOTPAR6 7.9 ± 7

TOTPAR6 9.5 ± 3.2

Time to max PID 30 (15 - 90)

No remedicating (1st dose) 30

Morphine consumption (1st dose) 5.2 ± 5.6

All active groups were produced significantly more analgesia than placebo, with dexketoprofen having better pain scores than diclofenac at times between 3 and 8 hours. Less morphine needed with dexketoprofen 50 mg and diclofenac than placebo and dexketoprofen 25 mg

SPID = summed pain intensity difference; TOTPAR = total pain relief

39 patients were excluded from efficacy analyses due to being included prior to a protocol amendment

A total of 310 adverse events were reported by 201 patients, most were mild to moderate in intensity (20 severe cases were reported), there were no statistically significant differences between groups. 11 serious adverse events were reported in 9 patients (1 with placebo, 1 with diclofenac, 3 with dex 25mg, and 4 with dex 50mg

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Abbreviations: RCT = randomised controlled trial; R = randomised; DB = double blind; WD = withdrawal or dropout; OPVS = Olsopn Pain validity Score; LOCF - last observation carried forward; ITT = intention to treat; N = number; LA = local anaesthetic; VAS = visual analogue scale; VRS = verbal rating scale; AE = adverse event; SPID = summed pain intensity difference; TOTPAR = total pain relief