Local Efficacy of Corticosteroids as an Adjuvant for Periarticular Cocktail Injection in Simultaneous Bilateral Total Knee Arthroplasty: A Prospective Randomized Double-blind Controlled Trial

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Research article

Keywords: Multimodal cocktail periarticular injection, corticosteroids, Betamethasone injections

Posted Date: August 24th, 2020

DOI: https://doi.org/10.21203/rs.3.rs-59553/v1

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Abstract

Background: Multimodal cocktail periarticular injection (MCPI) including corticosteroids is currently widely applied to reduce postoperative pain and swelling following total knee arthroplasty (TKA). However, the addition of steroids is controversial. This prospective, double-blinded, randomized, controlled trial compares the safety and efficacy of MCPI with or without corticosteroids.

Methods: A total of 60 patients (120 knees) who underwent simultaneous bilateral TKAs received periarticular injections with added betamethasone (7mg) in a randomly selected knee, and the other knee was injected without added corticosteroids. The visual analog scale (VAS) pain scores at rest and in motion, range of motion (ROM), thigh swelling, hospital for special surgery (HSS) score, and adverse events were compared between the 2 knees.

Results: There were no statistically significant differences in the visual analog scale score, ROM, thigh girth, HSS score, and complications between the 2 knees. The patients were unable to detect a difference in the functional recovery between their knees on postoperative day 3 or at the 3 month follow-up.

Conclusion: Betamethasone injections are ineffective locally for relieving pain, reducing swelling, and improving the postoperative ROM.

Trial registration: Chinese Clinical Trial Registry

Number: ChiCTR-OPC-17013503,

Date of Registration: 2017-11-23


Background

Total knee arthroplasty (TKA) is currently the most effective method for end-stage knee disease[1], however, patients who undergoing TKA often experience moderate to severe postoperative pain[2, 3]. Pain management post TKA is crucial to facilitate early mobilization, decreased length of stay, decreased opioid consumption and improved patient satisfaction[4, 5]. The application of periarticular injection to control the pain post TKA has gained wide popularity[2, 6]. The drugs mixed for this injection include a local anesthetic, an opioid, a nonsteroidal anti-inflammatory drugs (NSAIDs), adrenaline, etc. that are known together as a multimodal cocktail periarticular injection (MCPI)[6]. The safety and efficacy of the MCPI technique have been reported in previous trials that compared MCPI with other standard techniques for postoperative pain management, including epidural anesthesia[7], femoral nerve block[8] and intrathecal morphine[9]. However, there is still no gold standard for the formulation of "cocktail" drugs, especially for those the including of corticosteroids[6].
The addition of corticosteroids to MCPI might theoretically decrease the local inflammatory response post surgery. Several randomized controlled trials (RCTs) have compared the efficacy of MCPI with or without corticosteroids following TKA, but the outcomes were still controversial. Ikeuchi et al[10] had reported that MCPI with corticosteroids significantly reduced early pain and got rapid recovery post TKA. However, Kown et al[11] showed that corticosteroids just had an additional pain-relieving effect on the night of the operation. Christensen et al[12] stated that steroids can only reduce the length of the hospital stay following TKA, but it appears no to improve pain score or range of motion (ROM) in the early period after surgery. A systematic review by Zhao et al[13] concluded that the addition of corticosteroids to MCPI improved the analgesic effect and was shown to be highly safe. However, MCPI with steroids neither increased the early postoperative ROM nor the long-term ROM of the knees, nor reduced the postoperative drainage. Recently, two studies[14, 15] have reported that the systemic application of dexamethasone can achieve postoperative pain relief, reduced opioid consumption, and reduced nausea and vomiting post TKA.

Therefore, it is difficult to identify where the effect of locally used steroids comes from. Considering the theoretical increased risk of infection with local corticosteroid application[16] and knowledge that the existing RCTs compared the efficacy of MCPI with or without corticosteroids only in unilateral TKA patients, it seems reasonable to prefer the systemic application method. To address this, we performed a prospective, randomized, double-blind study in which we enrolled simultaneous bilateral TKA patients to determine 1) whether a MCPI containing a corticosteroid provides additional pain relief and functional recovery and; 2) whether a MCPI containing a corticosteroid increases perioperative complications.

**Methods**

**Study design**

Our study was a prospective, single-center, double-blinded, randomized, controlled trial. The study protocol was approved by our institutional review board and is registered in the Chinese Clinical Trial Registry (ChiCTR-OPC-17013503). Written informed consent and research authorization for participation in this study were obtained from each patient before surgery.

**Study population**

This trial included patients (age 18–80 years) undergoing simultaneous bilateral TKAs with osteoarthritis (OA)/rheumatoid arthritis (RA) from July 2017 to July 2018 in our hospital. Patients scheduled for unilateral TKA, staged bilateral TKA, or revision TKA were excluded. In addition, patients with contraindications to any of the study drugs due to an allergy, renal insufficiency, a history of cardiac disease, deep vein thrombosis, or surgery of the knee joint were excluded.

Among the 74 prospective cases, 60 met the study inclusion criteria and received the trial intervention. The preoperative diagnosis was osteoarthritis of the knee in all patients. The operating surgeon, operating staff, patients, physiotherapists, anesthetists and data collectors remained blinded for the study duration.
Interventions

In the operating room immediately preoperatively, the right or left knee was allocated to receive the MCPI with or without steroids using the envelope method. The circulating nurse performed the envelope selection before mixing the cocktail injection so that neither the patient nor the other staff knew the treatment details.

In the control knee, a 60-mL MCPI with (ropivacaine 200 mg/20 ml (AstraZeneca AB, Sweden), morphine 10 mg/1 ml, flurbiprofen axetil injection 50 mg/5 ml (Beijing Tide Pharmaceutical Co., Ltd., China), adrenaline 0.25 mg (1:1000), tranexamic acid 2000 mg/20 ml (Guangzhou Baiyunshan Pharmaceutical Co., Ltd., China), and 14 mL of normal saline solution) was prepared in three 20-mL syringes.

In the intervention knee, the 60-mL MCPI was the same as in the control knee, except Betamethasone 7 mg/1 ml (Schering-Plough Labo N.V., Belgium) was added to it.

The first 20 mL of the cocktail was injected into the posterior aspect of the capsule and structures of the knee joint immediately before implanting the prosthesis. After implantation, the remaining 40 mL of mixture was injected into the extensor mechanism, synovium, anterior capsule, pes anserius, retinaculum, periosteum, iliotibial band, and collateral ligaments.

Surgical procedures

All TKAs were performed under a tourniquet control inflated to 250 mm Hg by a senior orthopedic surgeon (JL). A medial parapatellar approach was utilized in all knees, and either a G-II PS (Smith & Nephew, Memphis, USA) or Nexgen PS (Zimmer, Limerick, Ireland) was inserted. Postoperatively, a standardized rehabilitation protocol was implemented. This included ROM exercises commencing on day one, with additional rehabilitation performed either on the ward or in the physiotherapy department until discharge. Postoperative chemical and mechanical thromboprophylaxis was instituted in all patients and consisted of thromboembolic deterrent stockings (TEDS) along with daily low molecular weight heparin subcutaneous injection until discharge. Vacuum wound drainage was applied in every patient with drain clamping for 4 hours, which was removed 48 hours later.

Intravenous second-generation cephalosporin (Cefuroxime 1.5 g, Glaxo Smith Kline, UK) was given preoperatively and every 12 hours for the first 24 hours postoperatively. We gave 1 g of tranexamic acid intravenously (Guangzhou Baiyunshan Pharmaceutical Co., Ltd., Guangzhou, China) just before skin incision in addition to adding tranexamic acid to the MCPI.

Multimodal pain management protocol

Patients were given 40 mg parecoxib (Dynastat, Pfizer, USA) diluted to 5 mL with 0.9% normal saline every 12 hours postoperatively for 3 days followed by an oral NSAIDs (60 mg of Loxoprofen Sodium Tablets Tid, Daiichi Sankyo, Japan). Patient-controlled analgesia (PCA) was used in all patients for 3 postoperative days with 1 mg morphine per press. There was no background or loading infusion of
morphine. For rescue analgesia, aminophenol oxycodone (Mallinckrodt Inc., US) was used when necessary.

**Outcome Measurements**

**Primary outcome**

Staff who were unaware of the treatment group to which either knee had been assigned conducted all assessments. The intensity of pain was rated using a 100 mm horizontal visual analog scale (VAS) in 100 mm increments, in which 0 mm represented no pain and 100 mm represented extreme pain. Time zero was defined as the time when the patients were awake at the postanesthesia care unit (PACU). Primary outcome measures included the VAS pain score at rest (preoperatively, time zero; postoperatively 6 h, 12 h, 24 h, day 2 and day 3), the VAS pain score in motion (postoperative 6 h, 12 h, 24 h, day 2 and day 3);

**Secondary outcomes**

The secondary outcomes were: 1) ROM of the knee during physical therapy (preoperatively and on postoperatively days 1, 3, 5, and 3 months); 2) thigh swelling of each leg[17] (2 points: the thigh girth at the patella superior border and at 5 cm proximal from the patella superior border; preoperatively and on postoperative days 1, 2, and 3) 3) HSS score (preoperatively and at 3 months postoperatively); 4) thigh skin temperature of each leg (5 cm proximal from the patella superior border; preoperatively and on postoperative days 1, 2, and 3) and 5) adverse events during the course of the trial, including wound complications, surgical site infection, peroneal nerve palsy, and deep venous thrombosis (DVT).

**Sample size calculation**

It was reported that a reduction of 20 points in the VAS pain scale score to be a clinically relevant difference[18]. To allow a dropout rate of 20% (8 participants), 51 patients were needed per group to detect a mean difference (and standard deviation) of 20 ± 33 points in the VAS pain scale score with a 2-sided 5% significance level and 80% power.

**Statistical analysis**

For statistical analysis, the Statistical Package for Social Sciences (SPSS Inc, IBM, version 22) was used. Statistical advice was gained before the planning of the study. For continuous variables, data are presented as the mean and the range and were compared between the groups using Student's t tests. For categorical variables, data are summarized as the frequency and proportion. Proportions were compared between the groups using a Fisher exact test for univariate analysis.

**Patient and Public Involvement:**

- The study protocol was discussed with patients in our department and got suggestions before getting the IRB approval.
- Patients were not involved in the recruitment to and conduct of the study.
The preliminary results had been disseminated to study participants via E-mail or written letter. The burden of the intervention were informed and assessed by patients themselves before participating in the trial. Patient advisers had been thanked in the contributorship statement/acknowledgements.

Results

Figure 1 provides a detailed flowchart summarizing the study recruitment and fieldwork. There were 4 men and 56 women. The mean age of patients was 65.1 ± 6.7 years (age range, 53–80 years), and the mean body mass index was 27.9 ± 3.4 kg/m² (Table 2).

Between the 2 knees, there was no significant difference in the preoperative status (VAS score at rest and in motion, preoperative ROM, and HSS score) or operative status (duration of surgery) (Table 1).

Table 1: Primary and Secondary Outcomes.
<table>
<thead>
<tr>
<th></th>
<th>Treated</th>
<th>control</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
<td>T</td>
<td>P</td>
</tr>
<tr>
<td>VAS pre-OP</td>
<td>54.3</td>
<td>9.4</td>
<td>55.4</td>
<td>9.3</td>
<td>-1.277</td>
<td>0.207</td>
</tr>
<tr>
<td>VAS(PACU)</td>
<td>27.2</td>
<td>3.8</td>
<td>26.7</td>
<td>4.1</td>
<td>0.864</td>
<td>0.391</td>
</tr>
<tr>
<td>Rest VAS 6 h post-OP</td>
<td>31.0</td>
<td>4.9</td>
<td>31.0</td>
<td>4.1</td>
<td>-0.086</td>
<td>0.932</td>
</tr>
<tr>
<td>Rest VAS12h post-OP</td>
<td>33.3</td>
<td>5.3</td>
<td>33.1</td>
<td>5.5</td>
<td>0.465</td>
<td>0.643</td>
</tr>
<tr>
<td>Rest VAS24h post-OP</td>
<td>34.2</td>
<td>6.5</td>
<td>34.3</td>
<td>6.5</td>
<td>-0.261</td>
<td>0.795</td>
</tr>
<tr>
<td>Rest VAS48h post-OP</td>
<td>33.1</td>
<td>8.4</td>
<td>34.1</td>
<td>6.7</td>
<td>-1.609</td>
<td>0.113</td>
</tr>
<tr>
<td>Rest VAS72h post-OP</td>
<td>34.0</td>
<td>7.4</td>
<td>34.0</td>
<td>6.23</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Motion VAS 6 h post-OP</td>
<td>47.4</td>
<td>5.1</td>
<td>47.5</td>
<td>4.4</td>
<td>-0.21</td>
<td>0.835</td>
</tr>
<tr>
<td>Motion VAS 12 h post-OP</td>
<td>49.1</td>
<td>5.0</td>
<td>49.6</td>
<td>4.4</td>
<td>-0.704</td>
<td>0.484</td>
</tr>
<tr>
<td>Motion VAS 24 h post-OP</td>
<td>50.25</td>
<td>4.994</td>
<td>50.83</td>
<td>4.618</td>
<td>-0.943</td>
<td>0.35</td>
</tr>
<tr>
<td>Motion VAS 48 h post-OP</td>
<td><strong>49.6</strong></td>
<td><strong>6.1</strong></td>
<td><strong>51.1</strong></td>
<td><strong>5.9</strong></td>
<td><strong>-2.809</strong></td>
<td><strong>0.007</strong></td>
</tr>
<tr>
<td>Motion VAS 72 h post-OP</td>
<td>49.3</td>
<td>4.9</td>
<td>49.8</td>
<td>4.8</td>
<td>-0.925</td>
<td>0.359</td>
</tr>
<tr>
<td>Thigh skin temperature(°C) pre-OP</td>
<td>36.4</td>
<td>0.18</td>
<td>36.5</td>
<td>0.20</td>
<td>-1.876</td>
<td>0.066</td>
</tr>
<tr>
<td>Thigh skin temperature(°C) 24 h post-OP</td>
<td>38.1</td>
<td>0.27</td>
<td>38.2</td>
<td>0.29</td>
<td>-2.22</td>
<td>0.03</td>
</tr>
<tr>
<td>Thigh skin temperature(°C) 48 h post-OP</td>
<td>38.1</td>
<td>0.22</td>
<td>38.2</td>
<td>0.26</td>
<td>-2.367</td>
<td>0.021</td>
</tr>
<tr>
<td>Thigh skin temperature(°C) 72 h post-OP</td>
<td>38.1</td>
<td>0.24</td>
<td>38.1</td>
<td>0.22</td>
<td>-1.867</td>
<td>0.067</td>
</tr>
<tr>
<td>Thigh circumference pre-OP(cm)</td>
<td>41.20</td>
<td>3.68</td>
<td>41.08</td>
<td>3.68</td>
<td>1.45</td>
<td>0.152</td>
</tr>
<tr>
<td>Thigh circumference(cm) 24 h post-OP</td>
<td>42.26</td>
<td>3.76</td>
<td>42.17</td>
<td>3.64</td>
<td>1.096</td>
<td>0.277</td>
</tr>
<tr>
<td>Thigh circumference(cm) 48 h post-OP</td>
<td>42.72</td>
<td>3.68</td>
<td>42.52</td>
<td>3.62</td>
<td>2.429</td>
<td>0.018</td>
</tr>
<tr>
<td>Thigh circumference(cm) 72 h post-OP</td>
<td>42.92</td>
<td>3.58</td>
<td>42.78</td>
<td>3.63</td>
<td>1.756</td>
<td>0.084</td>
</tr>
<tr>
<td>Ratio of the thigh girth 24 h post-OP</td>
<td>0.025</td>
<td>0.014</td>
<td>0.027</td>
<td>0.014</td>
<td>-0.779</td>
<td>0.439</td>
</tr>
<tr>
<td>Ratio of the thigh girth 48 h post-OP</td>
<td>0.037</td>
<td>0.017</td>
<td>0.036</td>
<td>0.016</td>
<td>0.826</td>
<td>0.412</td>
</tr>
<tr>
<td>Ratio of the thigh girth 72 h post-OP</td>
<td>0.042</td>
<td>0.018</td>
<td>0.042</td>
<td>0.019</td>
<td>0.199</td>
<td>0.843</td>
</tr>
<tr>
<td>HSS score pre-OP</td>
<td>35.4</td>
<td>3.6</td>
<td>36.0</td>
<td>3.2</td>
<td>-1.415</td>
<td>0.162</td>
</tr>
<tr>
<td>HSS score 3 months post-OP</td>
<td>89.2</td>
<td>3.8</td>
<td>89.0</td>
<td>3.6</td>
<td>0.379</td>
<td>0.706</td>
</tr>
</tbody>
</table>

VAS Visual Analogue Scale; ROM range of motion; OP operation; HSS hospital for special surgery; POD post operation day
Primary and outcome

There was no significant difference in the pain VAS score both at rest (Fig. 2) and in motion (Fig. 2) at any postoperative time point (Table 1).

Secondary outcome

There were no statistically significant differences in the secondary outcomes between the 2 knees (ROM (Fig. 5), HSS score (Fig. 4)), thigh swelling and thigh skin temperature at any postoperative time point (Fig. 3&Table 1). There was no difference between the two knees in POD1 and total drainage (Table 1). The patients were unable to detect a difference in the functional recovery between their knees on postoperative day 3 or at the 3 month follow-up (Table 3&Table 4).

Table 3
Patient self-assessment 3 days post surgery

<table>
<thead>
<tr>
<th>self-assessment</th>
<th>Prefer Steroids(+) side</th>
<th>Prefer Steroids(-) side</th>
</tr>
</thead>
<tbody>
<tr>
<td>Left side Steroids(+)</td>
<td>19</td>
<td>10</td>
</tr>
<tr>
<td>Right side Steroids(+)</td>
<td>17</td>
<td>14</td>
</tr>
</tbody>
</table>

60

P = 0.399 (chi-square = 0.712)
Table 4
Patient self-assessment 3 months post surgery

<table>
<thead>
<tr>
<th>Self-assessment</th>
<th>Prefer Steroids(+) side</th>
<th>Prefer Steroids(-) side</th>
</tr>
</thead>
<tbody>
<tr>
<td>Left side Steroids(+)</td>
<td>18</td>
<td>11</td>
</tr>
<tr>
<td>Right side Steroids(+)</td>
<td>20</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td></td>
<td>60</td>
</tr>
<tr>
<td>P = 0.113(chi-square = 0.514)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

No patients had clinical evidence of tense hemarthroses, subcutaneous hematomas, peroneal nerve palsies, surgical wound infections, skin necrosis or symptomatic VTEs up to 14 days after the surgery. No symptomatic DVT, PE and surgical site infection occurred in the short term (3 months) follow-up. Three patients received transfusion, and nineteen patients (31.8%) had vomiting episodes.

**Discussion**

This study found no significant differences in any primary or secondary outcomes: the VAS score at rest or in motion, ROM, and HSS scores were similar, regardless of the presence of betamethasone adding to the MCPI. And the patients were unable to detect a difference in the functional recovery between their knees on postoperative day 3 or at the 3 month follow-up. The rate of complications did not differ between the both knees. It seems that betamethasone was not locally associated with any significant pain relief or reduction of swelling in our study.

MCPI of anesthetic medications are a proven, effective adjunct to multimodal pain management protocols in the primary TKA [6]. While the combination of medications periarticular injected varies widely among randomized controlled trials, MCPI had been found to provide superior pain control vs the use of PCA[19] and femoral nerve blocks[20], and MCPI was equivalent to the use of a femoral-sciatic nerve block[21] after primary TKA.

One consideration is whether corticosteroids should be included in the MCPI. The evidence is conflicting. Two RCTs[12, 22] did not support the efficacy of corticosteroid in periarticular injection while the other four RCTs[10, 11, 23, 24] did. These conflicting results may be owing to: 1) different kind of corticosteroids added to the MCPI in different studies. For example, long-acting[25] or intermediate-acting[12] corticosteroids were used in the studies. 2) The surgical approach, and the application of a pneumatic tourniquet might have an effect on early postoperative pain. The main mechanism of reducing pain by corticosteroid was potentially through the decreased local inflammatory response following surgery. This method thereby resulted in decreased edema and blood loss owing to the reduced production of prostaglandins which cause vasodilation. Moreover, the patients may also enjoy a better knee ROM as corticosteroids reduce the postoperative fibrosis and scarring [26]; the systemic application
of corticosteroids can play the same role[15]. Thereby, a randomized, controlled trial include bilateral TKAs is needed to compare the local efficacy of corticosteroids through the periarticular injection method.

In our trial, corticosteroids were injected in only one knee of patients undergoing simultaneous bilateral TKA to identify the peripheral efficacy; However, we found no significant differences in primary and secondary outcomes. Though another possible option is increasing the dose of corticosteroids, it seems not practical because of the increased dose may further increase the risk of infection and patellar tendon rupture[22, 27]. Thus, the findings of this study indicate that the addition of corticosteroids to the MCPI may be unnecessary.

There is controversy about whether the cocktail mixture should be injected into the extensor mechanism. However, we did this in the same way as another study[18]. Chia et al[22] had suggested not because of increased risk of patellar tendon injury.

There were still a few limitations of the study. First, because periarticular injection and intravenous tranexamic acid were applied to prevent postoperative blood loss, the mild degree of swelling may have made it difficult to identify the effect of steroids in reducing inflammation. Second, to analyze the influence of steroids on surgical site infection, a larger sample size is needed. A recent meta-analysis[13] was underpowered for determining the safety of corticosteroid in periarticular injection, further studies are needed to answer this question. Third, the results of this study using betamethasone cannot be applied to other types of steroids. Pharmacological characteristics such as half-life and anti-inflammatory effects significantly differ among steroids. The advantage of this trial was that the surgeons, operating staff, patients, physiotherapists, ward nursing staff, and data collectors remained blinded to patients' knee status for the study duration.

**Conclusions**

In conclusion, adding steroids to an MCPI that included local anesthetic, NSAIDs, morphine, and epinephrine showed no additive local efficacy. The reported benefits of steroids in previous studies may be due to their systemic effects.

**Abbreviations**

MCPI
Multimodal cocktail periarticular injection
TKA
total knee arthroplasty
VAS
visual analog scale
HSS
hospital for special surgery
NSAIDs
Declarations

Ethics approval and consent to participate: The study protocol was approved by our institutional review board (Ethics Committee of Pekin Union Medical College Hospital, Number: ZS1433) and is registered in the Chinese Clinical Trial Registry (Number: ChiCTR-OPC-17013503). Written informed consent and research authorization for participation in this study were obtained from each patient before surgery. IRB see the attachments.

Consent for publication: All the authors listed have approved the publication.

Conflicts of interests: All the authors have nothing to disclose.

Funding: China International Medical Foundation

Authors' contributions: Dr Huiming PENG, Dr Wenda WANG and Dr Wei WANG. carried out the trial. Dr Huiming PENG and Dr Jin LIN wrote the manuscript with support from Dr Xisheng WENG and Dr Wengwei QIAN. Dr Jin LIN supervised the project.

Acknowledgements: The authors wish to thank several people. We would like to thank Dr Spangehl, Mark., M.D. for his help and suggestions for preparing the manuscript. Furthermore we would also like to thank Jinlong Wang Ph.D for statistical help. We would like to thank Na Gao as well for her assistance and guidance with this trial. Last, we would like to thank AJE for their English editing service. At last thanks for the founding support from China International Medical Foundation.

References


Figures
Figure 1

CONSORT Flow Diagram showing the flow of patients through each stage of the trial.
Figure 2

Pain VAS score at rest and on motion (mean and standard deviation) before and post total knee arthroplasty. Time zero is defined as the time immediately after surgery at PACU (Postanesthesia care unit). VAS, visual analog scale.

Figure 3

Ratio of the thigh girth at 10 cm proximal from the patella superior border before and following total knee arthroplasty. Skin temperature of the thigh at the patella superior border before and following total knee arthroplasty.
Figure 4

Knee HSS (Hospital for Special Surgery) score before and 3 months post total knee arthroplasty.

Figure 5

Knee ROM (range of motion) 5 days and 3 months post total knee arthroplasty.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- CONSORT2010checklist.docx