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Does an Early Post-Operative Pain Relieve Influence the Functional Outcome of Patients with Colles Fractures Treated with EG-Block System?

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Abstract.

Background: Distal Radius Fractures (DRFs) represent one of the most common elderly patient’s fractures. Often DRFs required surgical treatment based on instability of the fragments and due to the high functional demand from patients. A general agreement on the best pharmacological treatment in the post-operative is still missing. The present study describes the clinical outcome in patients who underwent surgery for Colles fracture using ES fixation osteosynthesis.

Methods: The present investigation represents a one center retrospective analysis. In this study, two different medical treatments were recognized, and groups consequently set (Group A: Ketoprofene 100 mg twice a day for 5 days, 59 patients; Group B: Tramadol 75 mg and Dexketoprofen 25 mg, 62 patients). Outcomes were the functionality of the affected wrist through AROM assessment and the evaluation of painkillers intake, pain itself and Quick-DASH.

Results: 121 patients were included in the present study. The pharma blending of Tramadol 75 mg and Dexketoprofen 25 mg resulted effective for the rapid recovery of the treated wrist motion. In fact, in the group B motion was better compared to group A (p<0.05) for any movement examined (flexion, extension, pronation, supination) until the last follow-up (70 days).

Conclusions: Associations of different painkillers are common, even if a general agreement on the most effective combination is still missing. Tramadol and Dexketoprofen provide a good clinical result, less side effects and a better functional recovery of the wrist motion. This guarantees a fewer social cost and a best management of post-operative physiotherapy.

Key words. Wrist fracture, Colles fracture, CRIF, Postoperative pain, pain killers.

Introduction.

Distal Radius Fracture is one of the most common injuries of the upper limb and they occur at all ages [1]. Extra-articular distal radius fractures (EDRF), known as Colles fractures, are one of the most common elderly patients fractures and the incidence is expected to increase with the aging of population, resulting in a non-negligible cost to society [2]. Functional impairment frequently occurs after EDRFs, due to inappropriate treatment [2,3].

Multiple choices for treatment remain possible [3]. Closed reduction and cast immobilization is an option, nevertheless loss of reduction can occur [3]. Furthermore, immobilization represents an obstacle to early movement recovery [2-4]. Surgical treatments include open reduction and internal fixation (plate and screw), which allows early mobilization, but it is considered by some authors as excessive, [3,5,6] exposing patients to avoidable complications due to internal fixation [7-9].

Closed reduction and percutaneous fixation represents even today a valid surgical procedure for EDRFs [3]. The Epibloc System (ES) is a percutaneous intramedullary fixation device used for this kind of fractures [5,6,10-12]. ES is reliable, simple, mini-invasive, cost-effective, easily removable and guarantees a stable fixation, allowing very early and safe active post-operative movement [5,10,11].

Most of patients experience significant post-operative pain, that does not allows early active movements and impairs functional results [2]. Pain killers could play an important role in the postoperative management; thus, pain reduction encourages active movement of the treated hand and wrist [13].

Many drugs could be used, but the choice of the best pain killer therapy is frequently related to surgeons’ and physicians’ personal beliefs [13-17]. In general, an active substance alone is commonly believed to be enough for pain control after a percutaneous surgical treatment. Acetaminophen and nonsteroidal anti-inflammatory drugs (NSAID) are believed to be adequate to treat osteoarticular pain [14]. However, when the maximum dose is reached, evident beneficial effects are not obtained, and side effects occur [14]. Analgesic combinations should be useful to obtain a longer and a more effective pain control, limiting the pain killer use and improving functional results [13-17]. Only a few studies in the literature specifically evaluate pain management protocols during post-operative period after wrist surgery [13,18].

The purpose of the present retrospective study was to investigate if the combined use of NSAIDs and opioid analgesic can improve clinical recovery, compared to the use of NSAIDs alone, in a cohort of patients who underwent wrist surgery with ES.

Materials and methods.

Study design and aim: The present investigation consists in a retrospective analysis on patients with EDRF referred at our Emergency Department and treated with percutaneous ES fixation from January 2015 to April 2019. The aim of the study is to evaluate if the use of an appropriate pain killer in the immediate post-operative period can facilitate early mobilization of the treated wrist and therefore improves functional outcomes. All patients signed a written consent concerning demographical

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and clinical data collection for scientific purposes according to institutional protocol. The study respects national ethical standards and the Helsinki Convention. Moreover, considering that the two therapies being studied are already used in the post-operative painkiller protocols in our institute, a formal ethical approval was not requested for this retrospective study.

**Institutional Database and data collection:** At our Emergency Department, patients triaged for wrist fracture are managed using a standardized data collection system. From these patients, we collected demographic, clinical and radiographic data (age, sex, BMI, anamnestic record, medical history, chronic therapies, smoke addiction, history of osteoporosis).

**Inclusion and exclusion criteria:** All patients with EDRF fracture (type 23-A2 and 23-A3 according to AO classification) [19] treated with closed reduction internal fixation (CRIF) through Epibloc system fixation were potentially eligible for the study. From the study were excluded: pregnant or breastfeeding woman; patient with: Alzheimer or Parkinson disease; patients with or with a history of gastric ulcer; patient with moderate to severe renal dysfunction (creatinine clearance < 60 ml/min), hepatopathies (MELD Score > 9), patients younger than 18 years, allergy, or contraindication to the study drugs. Patients who underwent surgery more than 7 days post trauma were excluded from this retrospective analysis. Patients who have not been compliant to the post-operative therapy and assessments were also excluded. Patients who reported a complex regional pain syndrome (CPRS) were excluded.

**Patients assignment and groups setting:** The patients were divided as follows based on the further pharmacological treatment received:

- **Group A:** Ketoprofen 100 mg twice a day for 5 days, from the first day after surgery. This group included 59 patients (48.8%, 38 F, 21 M)
- **Group B:** Tramadol 75 mg and Dexketoprofen 25 mg (in a single tab) twice a day for 5 days, from the first day after surgery. This group included 62 patients (51.2%, 44 F, 18 M).

Acetaminophen 1000 mg could be administered at most three times a day during all the post-operative period as a second-line analgesia (rescue drug).

A summary of demographic characteristic and comorbidity was reported in Table 1.

All patients received gastro-protective prophylaxis with Omeprazole 20 mg for 15 days.

The use of further painkillers was not restricted. In case of need they should call to the referring physician before taking any drugs. In this way the improper use of drugs was controlled, and the physicians could keep track of the drugs (painkillers) used by each patient. Each patient was required to keep track of all the drugs taken.

**Post-operative assessment:**

The complete post operative data setting for patients who undergo surgery (ES osteosynthesis) for distal radius fracture includes:

- 6 days post-operative clinical evaluation and plain radiographs (anterior-posterior view, lateral view of forearm), to exclude any further significant displacement. The compliance to the therapy was assessed. Clinical assessment performed: Active Range of Movement (AROM), pain, drug daily intake. Pain was assessed through visual analogue scale (VAS). Each patient has been verbally instructed on the home physiotherapy to be performed.
- 30 days post-operative clinical evaluation and plain radiographs (anterior-posterior view, lateral view of forearm), to confirm healing. Clinical assessment performed: AROM, pain, drug daily intake.
- Clinical evaluation after the removal of the wires (45 days after fracture). Active Range of Motion (AROM) of wrist and forearm is recorded, and specific hand and wrist physiotherapy was prescribed if patients reported 80% or less of AROM compared to the opposite side. Clinical assessment performed: AROM, pain, drug daily intake.
- 70 days post fracture clinical evaluation after the removal of the wires. AROM of wrist and forearm is recorded again. Clinical assessment performed: AROM, pain, drug daily intake, Quick DASH questionnaire outcome. The Quick DASH score represents a shortened version of the DASH Outcome Measure (composed by 30 items). The Quick DASH composed by 11 items is a rapid tool to measure physical function and symptoms in people with musculoskeletal disorders of the upper limb.
- Further assessment is considered on a case-by-case basis.

Data about the painkiller drugs intake were clustered a priori in two major period: before the removal of the wires (7–45 days post-surgery) and after the removal (45–70 days post-surgery).

**Surgical technique:**

All patients were surgically treated by two expert hand surgeons (G.T. and R.D.V.) [20]. All procedures were performed in plexus anesthesia and transient ischemia with pneumatic cuff. With radiographic guidance using a standard C-Arm device, two retrograde wires were introduced percutaneously by the second cortex; the external plate guarantees dynamicity to the implant through the elasticity of the wires, which compress the fractured surfaces.

<table>
<thead>
<tr>
<th>Demographics</th>
<th>Group A</th>
<th>Group B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>59</td>
<td>62</td>
</tr>
<tr>
<td>Gender</td>
<td>38 F, 21 M</td>
<td>44 F, 18 M</td>
</tr>
<tr>
<td>Age (years) (mean ± SD)</td>
<td>76.1 ± 9.2</td>
<td>77.2 ± 8.3</td>
</tr>
<tr>
<td>BMI (mean ± SD)</td>
<td>27.4 ± 2.7</td>
<td>28.1 ± 3.9</td>
</tr>
<tr>
<td>Dominant side</td>
<td>30 (50.8%)</td>
<td>25 (40.3%)</td>
</tr>
<tr>
<td>Smokers</td>
<td>10 (16.9%)</td>
<td>9 (14.5%)</td>
</tr>
<tr>
<td>History of confirmed osteoporosis</td>
<td>32 (54.2%)</td>
<td>29 (46.8%)</td>
</tr>
</tbody>
</table>

SD: standard deviation. BMI: body mass index.
After the surgery, no cast was applied. All patients were treated on average 5.6 (±1.4) days after the fracture trauma. The wires were removed after the fracture healed.

Outcomes: The primary outcome was the functionality of the affected wrist through AROM assessment. Secondary outcomes were the assessment of painkillers intake, pain itself (through Visual Analogue Scale, VAS) and Quick-DASH. Side effects were registered too.

Statistical analysis: Data are presented as mean and standard deviation. The Shapiro-Wilk test was used to check for normal distribution. Data were analyzed with Mann Whitney U (for non-parametric values) and Student's t-test (for parametric values) to compare continue variables. Statistical analysis was performed using the Chi-square test for categorical variables. The significance was established for a value of p <0.05. Dedicated software (SPSS v.20.0 software - SPSS Inc.; Chicago, IL) was employed. Only one decimal digit was reported, rounded up.

Results.

Population: A drop-out occurred in both groups. In group A (Ketoprofen alone), 5 patients discontinued the administration of drug because of side effects (1 case of headache, 4 cases of gastritis), 2 cases of CPRS occurred, 4 patients were lost at follow up. In group B (Tramadol + Dexketoprofen), 6 patients discontinued the administration of drug because of side effects (2 cases of gastritis, 4 cases of headache), 1 patient was lost at follow up, 2 cases of CPRS occurred. Finally, 48 patients (47.5%, 30 F, 18 M) were included in group A and 53 (52.5%, 36, 17 M) in group B.

Comparing the drop-out rate, the difference between group A and B was not statistically significant (p=0.541).

Healing occurred in all patients within 45 days after fracture. Wires removal was performed 36±3.9 days after surgery. No major complications were observed.

AROM outcome: In group A motion was better compared to group B (p<0.05) for any movement examined (flexion, extension, pronation, supination) until the last follow-up (70 days) (Table 2). During the 45 days evaluation of the AROM, in the group A 63.8% of patients need a specific hand and wrist physiotherapy prescription, while in the group B only 38.7% of patients, and this difference was statistically significant (p=0.0032).

Painkiller intake assessment: No statistical difference was reported in painkillers intake comparing group A and B before and after 45 days post-surgery (p>0.05) (Table 3). Forty-five days after surgery all patients had already undergone wire removal. Pain was significantly lower in group A before the wire removal (p<0.001).

No statistical differences were found in pain comparing the two groups after 45- and 70-days post-surgery (p>0.05) (Table 3).

Pain and functional assessment: After 70 days no statistical differences were revealed comparing group A and B (p>0.05), and all patient recovered a good function (Table 4).

Discussion.

Functional impairment frequently results from wrist and hand fractures, due to incorrect reduction of fracture and joint stiffness [2,3,21]. The two are not mutually exclusive. Hence very early hand and wrist motion should be encouraged.

Our study demonstrate how important is to choose from the earliest post-operative days the right painkiller therapy, to obtain a good clinical result as soon as possible.

Inflammation is an essential part of the early stage of bone fracture healing [22]. Mechanical damage to the bone cell membranes releases arachidonic acid, which is converted by cyclooxygenase-2 (COX-2) into pain-mediating pro-inflammatory prostaglandins [23]. Fracture hematoma, occurring immediately after injury due to broken vessels, is characterized by hypoxia and low pH and contains pro-inflammatory cytokines and cells [22]. COX-2 levels are increased in fracture

### Table 2. Active Range of Motion (AROM) outcome. All values are reported as a percentage to the contralateral side ± standard deviation (SD).

<table>
<thead>
<tr>
<th>AROM</th>
<th>Post operative time</th>
<th>Group A</th>
<th>Group B</th>
<th>Inter-group comparison (p value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexion</td>
<td>6 days</td>
<td>27.1±7.4</td>
<td>48.9±7.4</td>
<td>P&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>30 days</td>
<td>61.6±10.6</td>
<td>68.9±8.3</td>
<td>P&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>45 days</td>
<td>62.3±10.6</td>
<td>78.9±7.4</td>
<td>P&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>70 days</td>
<td>85.5±7.4</td>
<td>88.6±6.8</td>
<td>P=0.040</td>
</tr>
<tr>
<td>Extension</td>
<td>6 days</td>
<td>24.5±6.6</td>
<td>39.4±8.1</td>
<td>P&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>30 days</td>
<td>34.8±7.1</td>
<td>46.6±7.6</td>
<td>P&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>45 days</td>
<td>45.0±7.3</td>
<td>53.5±7.8</td>
<td>P&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>70 days</td>
<td>75.2±7.2</td>
<td>82.3±9.1</td>
<td>P&lt;0.001</td>
</tr>
<tr>
<td>Pronation</td>
<td>6 days</td>
<td>22.8±7.6</td>
<td>35.5±6.6</td>
<td>P&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>30 days</td>
<td>60.2±8.4</td>
<td>80.0±11.0</td>
<td>P&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>45 days</td>
<td>58.4±8.4</td>
<td>71.3±7.4</td>
<td>P&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>70 days</td>
<td>87.2±7.4</td>
<td>90.8±6.4</td>
<td>P=0.038</td>
</tr>
<tr>
<td>Supination</td>
<td>6 days</td>
<td>22.9±7.5</td>
<td>39.4±8.6</td>
<td>P&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>30 days</td>
<td>54.3±7.1</td>
<td>68.3±7.6</td>
<td>P&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>45 days</td>
<td>54.2±6.8</td>
<td>70.4±7.3</td>
<td>P&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>70 days</td>
<td>86.5±8.1</td>
<td>90.1±6.6</td>
<td>P=0.008</td>
</tr>
</tbody>
</table>
hematomas and, besides having pro-inflammatory activity, are also able to promote angiogenesis and the differentiation of mesenchymal cells into osteoblasts [24]. Accordingly, to use NSAIDs are not clearly discouraged to treat pain derived from a fracture, however caution is recommended [25,26].

To investigate pharmacological blend for treatment of this kind of pain should not be overlooked, in order to reduce the intake of NSAIDs [13,18]. Nevertheless, not much literature has been produced about the use of pharmacological blend in wrist fractures [13].

Several studies have shown that the combination of two or more analgesics allow the increase in efficacy and reduce the doses of the individual drugs, consequently the side effects [27,28]. In our series non statistical difference were reported concerning therapy compliance or discontinuation related to side effects. Heartburn, gastritis, and headache seems to be the most common side effects.

The combination of Tramadol and Dexketoprofen has been on the market for many years [16,29]. Tramadol analgesic efficacy is due to the long-lasting effect (t1/2 of about 6 hours). Furthermore, it is safer compared with other opioids. Indeed, Tramadol has not relevant effects on cardiovascular and pulmonary parameters, on the gastrointestinal transit, and has low addiction rate [29]. Moreover, it is safer compared with other opioids. Indeed, Tramadol has not relevant effects on cardiovascular and pulmonary parameters, on the gastrointestinal transit, and has low addiction rate [29].

In our study we observed significantly higher AROM values in pronation and supination after 4 weeks in the group treated with dexketoprofene + tramadol (group B), accordingly with the better function measured through Quick-DASH and the lower need to perform physiotherapy (63.8% vs. 38.7%).

This is a successful goal, considering that the cost for physiotherapy per patient in Group B has been reduced by almost a half.

These results underline how important is to improve movement. Patients of Group B have less pain until the third check, then the pain control data become the same as in group A (Table 4). Obviously, pain decreases after removing the wires in both groups.

The continuous need of additional painkillers after the first 6 days should not be overlooked [2]. Further studies are needed to investigate longer protocols for pain therapy in wrist fractures.

Moreover, patients clearly preferred to use acetaminophen to other drugs (table 3). This underlines how the use of acetaminophen is ingrained in popular culture as a first line painkiller [28]. In the same way the irrational fear for opiate drugs and NSAIDs can explain the choices of many of our patients. The suggestion of acetaminophen as preferred rescue drug could represent a bias in this study. This aspect could be further investigated in other studies.

Even if painkillers play a role in early functional recovery, the final recovery seems not to be affected by pain, in fact no difference were revealed between the two groups in term of function and movement at the last follow-up. This confirm that a proper surgical intervention and a proper physiotherapy are needed to obtain a good global result [2,3,19].

**Limitations.**

This study has a retrospective design and patients are not randomly assigned to each group. Thus, the sample could not reflect the real population. The follow up is short, however, the focus of the study was on short-term outcomes. Studies with longer follow ups are not discouraged.

We decide to exclude a priori patients suffering from post-operative CRPS, because they need for a more specific and longer pain therapy [30,31]. Nevertheless, in the future it could be interesting to investigate the role of dexketoprofene and tramadol in this kind of patients.

Moreover, a longer follow up can include further post operative late complications, such as synovitis and carpal tunnel syndrome and the following pain management [17,32].

**Conclusion.**

Sustained pain relief promotes the rapid restoration of motor function avoiding complications and further costs for the health of these patients. The combined use of dexketoprofene and

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**Table 3. Drug daily intake assessment.** *Second drug was Ketoprofene (100 mg) in group A and Tramadol (75 mg) and Dexketoprofene(25 mg) in group B. All values are reported as mean ± standard deviation (SD).*

<table>
<thead>
<tr>
<th>Post operative time</th>
<th>Drug</th>
<th>Mean daily intake - Group A</th>
<th>Mean daily intake - Group B</th>
<th>Inter-group comparison (p value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>7 – 45 days</td>
<td>Acetaminophen</td>
<td>2.0±0.5</td>
<td>2.0±0.5</td>
<td>P=0.995</td>
</tr>
<tr>
<td></td>
<td>Second drug*</td>
<td>0.3±0.4</td>
<td>0.2±0.4</td>
<td>P=0.714</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>0.2±0.4</td>
<td>0.2±0.4</td>
<td>P=0.717</td>
</tr>
<tr>
<td>45 days after surgery</td>
<td>Acetaminophen</td>
<td>1.2±0.4</td>
<td>1.2±0.4</td>
<td>P=0.718</td>
</tr>
<tr>
<td></td>
<td>Second drug*</td>
<td>0.2±0.4</td>
<td>0.2±0.4</td>
<td>P=0.720</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>0.1±0.3</td>
<td>0.1±0.2</td>
<td>P=0.673</td>
</tr>
</tbody>
</table>

**Table 4. Pain assessment through visual analogue scale (VAS) and functional assessment through DASH questionnaire.** All values are reported as mean ± standard deviation (SD).

<table>
<thead>
<tr>
<th>Pain</th>
<th>Post operative time</th>
<th>Group A</th>
<th>Group B</th>
<th>Inter-group comparison (p value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAS</td>
<td>6 days</td>
<td>7.2±1.0</td>
<td>5.3±1.1</td>
<td>P&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>30 days</td>
<td>4.9±0.9</td>
<td>3.9±0.7</td>
<td>P&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>45 days</td>
<td>3.2±1.1</td>
<td>3.1±1.3</td>
<td>P=0.576</td>
</tr>
<tr>
<td></td>
<td>70 days</td>
<td>1.3±0.7</td>
<td>1.2±0.7</td>
<td>P=0.230</td>
</tr>
<tr>
<td>Quick DASH</td>
<td>70 days</td>
<td>21.4±9.3</td>
<td>19.3±7.9</td>
<td>P=0.199</td>
</tr>
</tbody>
</table>
tramadol is encouraged to allow a better outcome both in terms of social costs and early recovery of wrist function.

REFERENCES