COMPARATIVE EXPLORATORY ANALYSIS ON EFFECTIVENESS, TOLERABILITY AND PATIENT/NURSE SATISFACTION WITH TWO NON-INVASIVE PATIENT CONTROLLED ANALGESIA TREATMENTS FOR ACUTE POST-OPERATIVE PAIN MANAGEMENT

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Background and Objectives:

Each year over 230 million major surgical operations take place worldwide with severe post-operative pain experienced by approximately 25% to 40% of patients undergoing surgery (Weiser 2008, Gerbershagen 2013). Inadequate post-operative pain management can increase patient morbidity, including delayed length of hospital stay, as well as pulmonary and cardiac complications, such as tachycardia, hypertension, myocardial ischaemia, and decreased alveolar ventilation (Barakat 2014, Ramsay 2004, S trovilis 2010). As post-operative pain delays patient discharge, increasing the time spent in hospital, it also leads to increased overall healthcare costs (Morrison 2003). Subsequent readmissions to hospital due to inadequate pain control will also incur high costs (Coley 2002).

Management of post-operative pain includes both patient controlled analgesia (PCA), where the patient has the autonomy to self-administer small fixed doses of opioids, according to their individual requirements, and non-PCA modalities. The benefits and risks of PCA over conventional non-PCA administration is a topic of ongoing research. PCA is considered the standard procedure for pain control in the inpatient setting and allows the patient to control their own pain. It also allows for the use of additional analgesics if required.

Methods:

A systematic literature review (SLR) was conducted to synthesise evidence, and included publications from January 2004 to March 2015, retrieved relevant efficacy and safety data for Zalviso and other treatments used in the management of moderate-to-severe acute post-operative pain in the hospital setting. To include in the SLR, studies had to meet predefined eligibility criteria. Evidence was obtained from randomised controlled trials (RCTs) irrespective of the blinding status. Studies evaluating adult patients clinically diagnosed with moderate-to-severe acute post-operative pain in a hospital setting following any type of surgery were included in the review, irrespective of gender and race. Through this SLR, Zalviso, as the only other non-invasive treatment, was identified as a comparator. However, due to eligibility criteria concerning baseline pain severity (moderate-to-severe pain only), several studies evaluating Zalviso were excluded from the SLR. As further research, this exploratory analysis included studies evaluating Zalviso or lonys versus an active comparator, ZV morphine PCA.

For Patient Global Assessment of the method of pain control (PGA) scores of "good" or "excellent" the results were significantly in favour of Zalviso at 24 hours (RR: 1.17, 95% CI: 1.02 to 1.34) and numerically in favour of Zalviso at 48 and 72 hours. Furthermore, regarding the Healthcare Professional Global Assessment (HPGA) results were significantly in favour of Zalviso at 24 hours (RR: 1.21, 95% CI: 1.07 to 1.36) and 48 hours (RR: 1.2, 95% CI: 1.04 to 1.38) and numerically in favour of Zalviso at the 72-hour time point (RR: 1.13, 95% CI: 0.98 to 1.29). (Figure 3)

Regarding tolerance outcomes, "Withdrawal due to any cause" results indicated a numerically lower risk for Zalviso (RR: 0.65, 95% CI: 0.42 to 1.02) and the risk of withdrawal decreases with both treatments (RR: 1.02, 95% CI: 0.47 to 2.22) the risk of withdrawal due to lack of efficacy was significantly lower with Zalviso (RR: 0.45, 95% CI: 0.21 to 0.90). (Figure 5)

Conclusions:

Zalviso is a non-invasive patient-controlled analgesia system utilizing sublingual sufentanil tablets to treat acute moderate to severe post-operative pain in the hospital setting.

For all the analyzed disposition and satisfaction endpoints Zalviso showed significant or numerically advantageous indicating to be the preferred non-invasive patient controlled analgesia treatment for post-operative pain.

References:


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