HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
SUMMARY
6 JANUARY 2021
The legally binding text is the original French opinion version

lidocaine hydrochloride
XYLOCARD 20 mg/ml INTRAVENOUS solution for injection

New indication

Key points

Favourable opinion for reimbursement in perioperative analgesia for laparoscopic or open abdominal surgery (such as colorectal surgery, prostatectomy, cholecystectomy).

What therapeutic improvement?

No clinical added value in the therapeutic strategy.

Role in the care pathway?

The current management of postoperative and recovery pain is based on the establishment of protocols of treatments with multi-modal analgesic regimen comprising non-morphine analgesics and/or loco-regional analgesia in order to allow postoperative morphine sparing.

The use of opioids (in particular morphine) may be considered in the event of severe postoperative pain or in the event of inadequate pain relief using non-opioid analgesics. The opioids used for postoperative analgesia are associated with numerous dose-dependent adverse effects, in particular nausea, vomiting, constipation, hyperalgesia, which may delay postoperative recovery and increase postoperative ileus. They can also cause opioid dependence.

Thoracic epidural analgesia is considered to be the reference in patients undergoing open abdominal surgery to improve postoperative recovery. However, this practice is not devoid of risks (postoperative hypotension, urinary retention, etc.) and is contraindicated in certain situations.

Another proprietary medicinal product based on lidocaine for injection is currently authorised in the prevention of postoperative pain, in particular to accelerate the resumption of intestinal transit following abdominal surgery: LIDOCAINE AGUETTANT 10 mg/ml PRESERVATIVE-FREE solution for injection.

Role of the medicinal product in the care pathway

XYLOCARD 20 mg/ml INTRAVENOUS (lidocaine hydrochloride) is a first-line treatment in perioperative analgesia for laparoscopic or open abdominal surgery (such as colorectal surgery, prostatectomy, cholecystectomy).

The Committee highlights the risk of adverse effects with intravenous lidocaine, particularly in the event of bolus administration.

The Committee points out that, in accordance with the Summary of Product Characteristics (SPC), continuous infusion of intravenous lidocaine should be stopped at the end of the surgical procedure. If infusion needs to be continued postoperatively (in the postoperative recovery room, intensive care or high-dependency unit), patient must be maintained under continuous electrocardiographic monitoring, without exceeding a period of 24 hours after surgery.

◗ Recommendations

The Committee highlights the fact that, unlike the proprietary medicinal product LIDOCAINE AGUETTANT containing 10 mg/ml, the strength of the proprietary medicinal product XYLOCARD INTRAVENOUS (lidocaine hydrochloride) in this indication is 20 mg/ml.

Only this 20 mg/ml strength is concerned by this indication. The XYLOCARD INTRAVEINOUS (lidocaine hydrochloride) 50 mg/ml strength currently available is only authorised in the treatment and prevention of recurrences of ventricular rhythm disorders.

COMMITTEE'S CONCLUSIONS

Clinical benefit

◗ Postoperative pain is frequent and its intensity depends on the surgical procedure and patient sensitivity. The interruption of postoperative intestinal transit in abdominal surgery is one of the main unfavourable factors slowing convalescence and therefore likely to increase the length of hospital stay.

◗ XYLOCARD 20 mg/ml INTRAVENOUS (lidocaine hydrochloride) is a preventive treatment for postoperative pain following abdominal surgery.

◗ The efficacy/adverse effects ratio of intravenous lidocaine is high in this indication.

◗ There are medicinal alternatives.

◗ XYLOCARD 20 mg/ml INTRAVENOUS (lidocaine hydrochloride) is a first-line treatment for the prevention of postoperative pain, particularly to reduce opioid use and promote the resumption of intestinal transit following abdominal surgery.

◗ Public health impact

Considering:

- the seriousness of postoperative pain and/or the slowing of intestinal transit following abdominal surgery,
- their incidence,
- the partially met medical need,
- the lack of additional response to the identified need due to:
  - limited meta-analysis data suggesting moderate efficacy of IV lidocaine compared to placebo,
  - the lack of quality of life data,
- the lack of robust data on a possible impact on the organisation of care, and in particular on the reduction in the duration of hospitalisation,

XYLOCARD 20 mg/ml INTRAVENOUS (lidocaine hydrochloride) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of XYLOCARD 20 mg/ml INTRAVENOUS (lidocaine hydrochloride) is substantial in the new MA indication.

The Committee issues a favourable opinion for inclusion in the hospital formulary list of reimbursed proprietary medicinal products approved for use in the new indication and at the MA dosages.

Clinical Added Value

Considering:

- **meta-analysis data suggesting moderate perioperative efficacy of IV lidocaine compared to placebo/absence of treatment on early postoperative pain scores, the incidence of postoperative ileus and postoperative opioid use,**
- **the high level of heterogeneity reported between studies, thereby limiting these results,**

the Committee considers that XYLOCARD 20 mg/ml INTRAVENOUS (lidocaine hydrochloride) provides no clinical added value (CAV V) in the perioperative analgesia strategy for laparoscopic or open abdominal surgery (such as colorectal surgery, prostatectomy, cholecystectomy).