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Brachytherapy, Sedation *Vs* Spinal Analgesia, about 99 Cases

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Abstract

Introduction: The installation of brachyherapy applicator is a painful invasive procedure requiring anesthesia. In this study, we propose to compare intravenous anesthesia with spontaneous ventilation to an intrathecal analgesic protocol with local anesthetics and fentanyl. The main objective was to demonstrate the superiority of spinal analgesia in terms of per and postoperative analgesia during patient mobilization for CT scan. We performed a randomized clinical trial for women patients ASA 1 and 2 programmed for brachytherapy, then we divided them into 2 groups. Group 1: Have benefited from intravenous anesthesia by propofol titration with fentanyl. Group 2: Benefited from spinal analgesia with bupivacaine 5 mg and fentanyl 25 mg. Then we collected demographic data, quality of anesthesia (Ramsay score for level of sedation, analgesia level by analogical visual scale score), hemodynamic and respiratory parameters, anesthetics events , duration of anesthetic acts, pain during mobilization.

Keywords: Brachytherapy • Sedation • Women • Spinal analgesia

Introduction

Brachytherapy is an intracavitary radiotherapy technique witch revolutionized the management of many cancers, especially cervical cancer. This procedure is painful, uncomfortable and requires patient cooperation. It is therefore necessarily to perform under anesthesia. At the National Institute of Oncology, intravenous sedation has been the technique usually used to anesthetize patients during examination procedures, placement of applicators without any post-operative analgesic monitoring. In view of the desire to improve the quality of care, the aim was to set up anesthetic protocols to improve the situation. We have initiated a comparative feasibility study of spinal analgesia for local anesthetics and sedation as the gold standard technique. The aim was to determine whether spinal analgesia allows the applicator procedure to be performed and demonstrate the superiority of rachianalgesia in terms of postoperative analgesia during patient mobilization [1].

Materials and Methods

This is an open randomized clinical trial involving a population of women with cervical cancer requiring the placement of intra-cavity applicators for Brachytherapy. The exclusion criteria were patients who had refused one of the techniques, a coagulation disorder or an ongoing anticoagulant treatment (patients being managed on an outpatient basis, the management of perioperative anticoagulants risks modifications of the protocol after randomization), chronic pain under treatment, spinal pathology, intracranial hyperpressure, known allergy to one of the anesthetics and psychiatric pathology [2]. The draw of the patients was realized. Group 1 was the Sedation group and group 2 was the spinal analgesia group. All the patients signed a consent, elaborated and confirmed by ethics and deontology committee of the establishment.

- In group 1, intravenous anesthesia with conservative spontaneous ventilation was performed with an injection of 2 mg/kg of propofol and 1 µg/kg of fentanyl to obtain a ramsay score of 4 with spontaneous ventilation (EtCO2<40 mmHg). Maintenance was performed by reinjection of propofol and postoperative analgesia was provided by paracetamol.
- In group 2, a 5% hyperbaric bupivacaine rachianesthesia was performed by injection into the L4-L5 or L3-L4 spaces of 5 mg of bupivacaine associated with 25 µg of fentanyl. In order to achieve a Visual Analogue Scale score (VAS) of 0, a bromage score of 0 [3].

The data was collected by the anesthetist doctor. Processed by the SPSS 20 software. The quantitative variables were expressed as mean ± standard deviation or median. Qualitative variables were expressed in number (percentage). Contingency tables were used for the qualitative variables and for the coded quantitative variables. Chi² and Fisher tests were used. The alpha risk was established at 0.05.

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Results

Descriptive study

Over a 17-week period, 145 patients were treated with Brachytherapy. Forty-six patients were excluded: ASA score >2 (n=5), the patient who refused rachianalgesia (n=6). Contraindication to rachianalgesia (n=35, anticoagulant treatment, herniated disc, secondary cerebral localization, chronic pain).

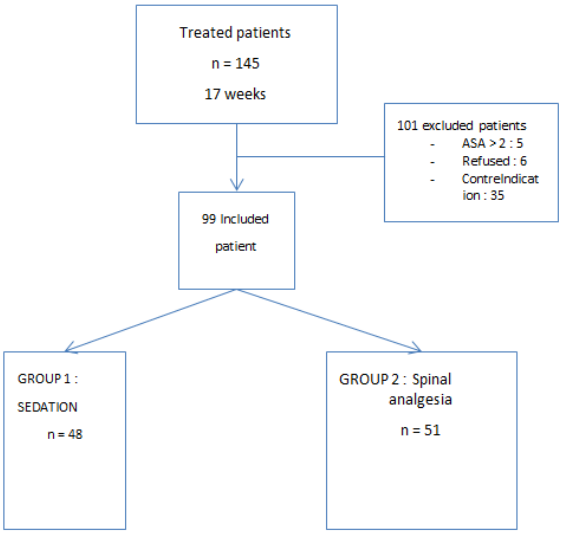

Figure 1. Study flowchart.

The median age of the patients was 48 (30; 61).

- All patients were treated for curative purposes. Only 1 patient had cervical localization secondary.
- 9 patients had been operated on previously, 3 for a cancerous disease (one for her uterine cancer). These patients had general anesthesia in the majority of cases (73.6%).
- Twenty-one patients had benefited from anesthesia for caesarean section or a non-surgical procedure (endoscopic, orthopedic). A comparative study of these general population data was performed between patients in groups 1 and 2. These results are shown in Table 1. We note the absence of a statistically significant difference in the status and preoperative antecedents of patients in both groups.

Analytique study

The study of the durations of the procedures is statistically comparable between groups 1 and 2. The analysis of the duration of anesthetic induction is longer in group 2 than in group 1 (12.1 ± 3.2 *vs* 7.1 ± 2.2, p=0.045). On the other hand, transhipment after complete awakening (Aldrette score at 12/12 or 11/12 in group 2) is faster in the spinal analgesia group (3.1 ± 2.2 vs 9.4 ± 5.8 p=0.038). During the performance of the anesthetic act, changes in the constants remained within the normal range after induction for 89 cases (89.9%), 95 cases (95.9%) intraoperatively and 98 cases (98.9%) on discharge from the patient ; without there being any difference between the 2 groups. The technique used achieved its anesthetic goals in all cases (n = 48) in group 1 and in 50 cases (98%) in group 2. The collection of adverse events related to anesthesia accounted for a total of 9 events (respectively 6 in group 1 and 3 in group 2) occurred in 6 patients: 3 cases arterial hypotension 1 case of desaturation with inhalation (1 vs 0), 4 cases of nausea and / or vomiting. Evaluation of analgesia during:

- The mobilization found in group 1, 40 cases (83.3%) with VAS <4 versus 51 cases (100%) in group 2 (p=0.055).
- Arriving at the CT scan room, only 12 cases (25%) were found in group 1 versus 45 cases (88.2%) in group 2 (p=0.02).

All patients in group 1 (n=48) required additional analgesia (according to established protocols), wake-up mobilization and scanner room. In group 2 (n=51), only 1 patient on awakening (2%) and 15 patients on CT scan (29.5%) required an intravenous analgesic supplement (p<0.001).

Characteristics	Group 1	Group 2	P
	n = 48	n = 51	
Bromage score at 0 transhipment	48(100)	51(100)	NS
EVA at transhipment <4	40(83,3)	51(100)	0.055
EVA=0-1	0 (0)	50(98)	<0.001
EVA=2-3	40(100)	1(2)	<0.001
EVA at the scanner <4	12(25)	45(88,2)	<0.02
EVA=0-1	0(0)	36(80)	<0.001
EVA=2-3	12(100)	9(20)	<0.01

Table 1. Clinical data at postoperative mobilization.

Discussion

Intra-cavitary radiotherapy has revolutionized the management of cervical cancer. It involves the insertion of an intrauterine vector (or applicator) through the vulva, the vagina, the cervix and positioned against the uterine fundus. In order to diffuse isotope radio at the level of diseased uterine tissues. This procedure requires positioning the patient in a lithotomy position (or gynecological position) and then exposing the intravaginal cavity. After measuring the depth of the uterus by a hysterometer, the different applicators (metal conduit) are introduced and fixed together. These different times require a relaxation of muscle and cooperation of the patient. There are various anesthetic techniques that can be used for the placement of applicators. Each of these techniques has advantages and disadvantages. In our context, sedation has been the standard technique used at the National Institute of Oncology since the beginning of its activity in 1984 [4]. The conditions of anesthesia and operating procedures improved 4 years ago with the construction of an operating room dedicated to Brachytherapy and equipped with a standard anesthesia station, allowing performing all types of anesthetic acts in a safe way.

As part of a process of diversification of anesthetic techniques used to have a technical alternative, we decided to conduct a feasibility study comparing the usual technique (sedation) to spinal

analgesia.The results show that spinal analgesia is a technique for performing the act of setting up an applicator by Brachytherapy operator without hindering the duration of the act, its safety, or the comfort of the Brachytherapy operator. 98% of patients had their applicators placed without the need for additional intravenous anesthesia. In addition, the analgesia obtained during surgery achieved its objectives: VAS at 0 during the procedure, while maintaining a bromage score of 0. Similarly, the mobility of the patient did not hinder the gesture; this is perceptible by the fact that no technical complication has been reported. In addition this allowed the patient to participate in its mobilization and its installation on the table and cart with better analgesia in comparison with the sedation group. The satisfaction of the paramedical staff has also been reported. Adverse effects related to anesthetic techniques studied in both groups, whether hemodynamic cardiovascular, respiratory, neurological, allergic or perioperative nausea and vomiting [5].

Regarding the effects of anesthesia, in both techniques, no serious cardiovascular events were observed. The number of significant hemodynamic variations was small and the analysis of the two groups found no difference between intravenous anesthesia and spinal analgesia. Only one respiratory event occurred in the 'sedation' group, patient had vomiting with inhalation , causing desaturation. No neurological complications were noted. On the other hand we did not notice any serious allergic reaction. However 38 patients (74.5%) in group 2 had a minor cough with pruritus without skin reaction following spinal analgesia. These events were attributed to the use of intrathecal fentanyl. One of the major contributions of this work is related to the advantage of the locoregional technique in the prolongation of pelvic analgesia during mobilization on awakening of the patient and until transport to the radiology department for the realization (with a new transhipment) of a control imagery (<20 minutes from the exit, from the operating room). Our results showed that spinal analgesia significantly relieved the pain of a larger number of patients. In addition, this has made it possible to dispense with an intravenous analgesic of palliate 1 (paracetamol, NSAID or Nefopam) in addition to the exit of the operating room.

It is reported in the literature that the management of postoperative analgesia is common intravenously. The protocols used are based on those of postoperative pain in pelvic gynecological surgery. In our context, we opted for spinal analgesia with opioid addiction in a future protocol to study the quality of management of pain postoperatively at a distance from the block procedure. This review concludes that although limited, locoregional anesthesia appears to be beneficial for the comfort, analgesia and safety of patients admitted to Brachytherapy service. No steroidients anti nflammatory and paracetamol and especially their association with codeine phosphate contributes to a multimodal management of pain. It responds in particular to the painful sensation like cramp. It is suggested that the use of NSAIDs will reduce the prescription of opioids for pain management.

Limitations of the Study

This clinical work aimed to determine the feasibility of a routine locoregional anesthesia protocol as an alternative to sedation. This study made it possible to demonstrate its feasibility in a safe way with satisfactory results beyond our expectations regarding the effectiveness of analgesia per and post operative. Only consistent clinical data (hemodynamic, respiratory, and adverse effects) were evaluated in both groups. This limit is insurmountable from a technical point of view, making the test necessarily an open quality.

Conclusion

Since this study, spinal analgesia with bupivacaine has become the standard technique in our practice, leaving propofol sedation as the alternative. Several protocols have been tried and raise the issue of the best prescription. However, there is a limit in the methodology of the work and It concerns the criterion of judgment. Indeed, we compared two different anesthetic techniques, which can not have the same objective comparison criterion.

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