

EVALUATION OF THE OPTIMAL POSITIONING OF SUBCUTANEOUS BUTTERFLY WHEN ADMINISTERING INJECTABLE OPIOIDS IN CANCER PATIENTS

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Abstract

Background and aims. The increasing number of cancer patients, together with the development of new palliative care services in Romania, warrants the evaluation of nursing strategies meant to improve the level of comfort of patients who are suffering from advanced cancer.

The main objective of the study was to evaluate the optimal positioning of the subcutaneous (sc) butterfly, in accordance with its resistance in the insertion tissue, the local complications that may occur, and the evaluation of the time of resistance at the insertion site (puncture) with the daily frequency of injectable opioid administration.

Methods. A prospective experimental pilot study was designed and conducted between January and May 2011. Patients admitted to the Hospice Casa Sperantei (Brasov, Romania) with moderate or severe cancer pain, who were receiving subcutaneously opioids, over the age of 18, with normal body index ranging from 18.5 – 22.0, were assigned randomly to one of two groups, after signing the informed consent. In group one, the butterfly was positioned with the needle bevel up – this was considered to be the control group as this modality of inserting the needle is considered standard practice; in group two the butterfly was positioned with the needle bevel down – experimental group. The drugs used for pain relief were sc tramadol for moderate pain and sc morphine for severe pain.

Results. Our research supported the hypothesis that the occurrence of local complications coincides with the decrease of sc butterfly resistance in time at the place of insertion, and the sc butterfly has a higher rate of resistance in time at the insertion site if the frequency of injectable opioids administration is lower (twice per day).

Conclusion. The positioning of the butterflies with the bevel down (experimental group) is associated with a longer resistance in time at the site of insertion, and causes fewer local complications compared to the sc butterflies positioned with the bevel up (control group).

Keywords: subcutaneous butterfly, needle bevel positioning, cancer, opioids

Background and aims

The growth in the number of cancer patients, together with the development of new palliative care services in Romania [1], warrants the evaluation of nursing strategies meant to improve the level of comfort of patients who are suffering from advanced cancer. Pain is one of the most frequent symptoms in patients with advanced cancer [2], and the use of opioids is a standard practice with patients who are in pain [3]. Oral opioids are the gold standard [4,5] but several eastern European countries have access only to injectable morphine as medicine to treat severe pain [6]. To maximize comfort, instead of using intramuscular or intravenous route, the subcutaneous administration with an indwelling subcutaneous butterfly needle has been proved to be painless, efficient and easy to use [7,8]. For countries with limited resources it is a useful method of administering parenteral medication as it has a lower cost than intravenous pumps and it also gives patients and families the possibility, with some training, to administer the drugs themselves [9].

The main objective of this study was to evaluate the optimal positioning of the subcutaneous (sc) butterfly, in accordance with its resistance in the insertion tissue, the local complications that occur and the evaluation of the time of resistance at the insertion site (puncture) with the daily frequency of injectable opioid administration.

Methods

A prospective experimental pilot study was designed. Patients admitted to the Hospice Casa Sperantei with moderate or severe cancer pain and who were receiving subcutaneously opioids, over the age of 18, with normal body index ranging from 18.5-22.0, were assigned randomly, after signing the informed consent, to one of two groups. In group one, the butterfly was positioned with the needle bevel up – this was considered to be the control group as this modality of inserting the needle is considered standard practice [10,11,12,13]; in group two the butterfly was positioned with the needle bevel down - experimental group. The drugs used for pain relief were sc tramadol for moderate pain and sc Morphine for severe pain.

Data from patients were collected between January and May 2011, in a sample of 100 adult cancer patients. The study was approved by the hospice's ethics committee. Correlations between the frequency of administration of opioids and the occurrence of local complications, and between the occurrence of local complications and the time of resistance of the subcutaneous butterfly at the insertion site, were established.

The hypothesis is that there is a significant positive relation between the frequency of injectable opioid administration and the occurrence of local complications, respectively a negative relation between the occurrence of complications and the time of resistance of the subcutaneous butterfly at the insertion place. In addition,

we wanted to establish which of the two butterfly insertion positions (butterfly with the needle bevel up or down) had a longer time of resistance at the insertion site with respect to incidence of complications.

The data collected has been analyzed with SPSS 11.

Results

Characteristics of the patients in the study

The study was conducted between January and May 2011, on a sample of 100 adult cancer patients who were all outpatients of Hospice Casa Sperantei. The distribution of the study group according to gender shows a predominance of male over female gender. The majority of participants resided in rural areas (see Table I). This is consistent with accessibility to medical care and the lower availability of clinicians in the Romanian health care system [14]. The largest age group was represented by patients between 50 and 80 years. There was no statistical difference in the composition of the control and study group concerning gender and place of residence. Concerning the age of the patients in the study and control group there were significantly fewer patients in the age group of 70-79 years ($p=0.05$) in the control group compared with the study group.

The patients included in the study had most frequently broncho-pulmonary cancer (19%), colon cancer (15%) and breast cancer (13%). There was no significant difference between the study and control group in terms of type of cancer. (see Table II).

Pain characteristics in the study population

In the 100 cancer patients, the main cause of pain was visceral 47 patients (47%), somatic pain 43 (43%), and only 10 presented with neuropathic pain (10%); the patients with moderate pain represented approximately two-thirds of the total number of patients and one-third suffered severe pain (Table III). There was an even distribution of patients in the experimental and control group concerning type and intensity of pain.

Use of analgesics in the study population

In the sample studied, the two opioids, tramadol hydrochloride and morphine, were administered in different proportions; tramadol, as a weak opioid, was administered for moderate pain and was given in almost two-thirds of the patients during the study period (see Table IV). Morphine, given through the subcutaneous route, was the drug used for patients who had severe pain. There was no significant difference between study and control group in terms of type of medication received for pain.

The two analgesics had a different frequency in administration: 2, 3 or 4 times per day for tramadol hydrochloride and 2, 3, 4 or 6 times per day for morphine. (see Table V). This can be explained through the different pharmacokinetics of the two opioids, tramadol [15] having a longer half time compared with morphine [16], it was an expected result to see fewer administrations per day

compared to morphine. There was no difference between study and control group concerning the frequency of administration of the drugs.

Complications with subcutaneous administration of analgesics

The frequency of local complications for all the patients in the study was 52%. The most frequent complication encountered when administering analgesics in patients with cancer was subcutaneous tissue indurations (56% for the whole sample) followed by redness and bleeding. We encountered no infection or accidental needle pulling in our study. The complications encountered are presented in Table VI.

There were also significant differences between the possibility of the occurrence of local complications among the patients in the two subgroups. The mean of local complications occurrence was significantly higher/significantly lower ($t=6.69$, $p<.001$) in the study group – patients who had the sc butterfly positioned with the bevel down (mean=1.24, close to the first version, ‘no complications’) compared with the control group – patients that had the sc butterfly positioned with the bevel up (mean=1.80, close to the second version, ‘with complications’). On average, the sc butterflies positioned with the bevel down caused fewer local complications, compared with the sc butterflies positioned with the bevel up.

Positioning of the butterfly

In daily practice, the sc butterfly positioning is done with the needle bevel facing up. Evidence from this study comparing any significant difference in regard to the resistance of the sc butterflies and the occurrence of local complications in both modalities of positioning the bevel of the needle, could be used to support nurses in their daily practice.

The design of the subset started with the separation of the study sample into two groups; half of the patients had the sc butterfly inserted with the bevel up (50%) – control group – and the other half with the bevel down (50%) – experimental group. We found significant differences between the resistance of the sc butterfly at the insertion site in the two subgroups; the patients who had the sc butterfly inserted with the bevel up and the patients who had the sc butterfly inserted with the bevel down (Figure 1).

The mean of sc butterfly resistance at the place

of insertion was significantly higher ($t=10.48$, $p<.01$) in the care of patients who had the sc butterfly positioned with the **bevel down** (mean=2.88, close to 3 – the third version, meaning ‘seven to nine days’) compared to the patients who had the sc butterfly positioned with the bevel up (mean=2.00, meaning ‘four to six days’).

Analysis performed on the whole sample of patients Correlation between complications and frequency of administration

In order to determine if there is a significant relationship between the frequency of administration of subcutaneous analgesics and the occurrence of local complications, the daily rate of administration of each drug was analyzed separately. The frequencies of administration were two, three or four times per day for tramadol and two, three, four or six times per day for morphine. The incidence of local complications was evaluated using the terms: ‘no complications’ and ‘with complications’. A positive correlation existed between the daily frequency of the administration of opioids and the occurrence of local complications at the administration site with a p-value of .049 when using tramadol. No correlation was noted when administering morphine (p-value .316). We expected to have an increase in the occurrence of complication with higher numbers of administration and our results support this assumption. The difference seen in the appearance of complications between morphine and tramadol might relate to better subcutaneous tolerance for morphine, or it might be the result of the small sample size in our study.

Resistance in time at the injection site

The administration of opioids in cancer patients is a long-lasting process, and for this reason the use of a subcutaneous butterfly is a necessary procedure to enhance the comfort and the quality of life of the patient in countries where there are no oral opioids available. The resistance in time for maintaining the sc butterfly varied between one and 12 days; in general, most of the patients had the sc butterfly maintained for four to six days (53%) (see Table VII).

Our data supports the hypothesis that a significant negative correlation exists between the occurrence of local complications and the resistance in time for maintaining the subcutaneous butterfly at the insertion site with a p-value of .001, $r= -0.558$.

Table I. Demographical data.

Gender	Male	Female	Differences between study and control group			
• Whole sample	53	47				
• Control group	25	25	Not significant			
• Study group	28	22	Not significant			
Residence	Urban	Rural	Differences between study and control group			
• Whole sample	62	38				
• Control group	29	21	Not significant			
• Study group	33	17	Not significant			
Age	30-39	40-49	50-59	60-69	70-79	over 80
• Whole sample	6	11	22	21	23	17
• Control group	3	6	10	12	9 (p=0.05)	10
• Study group	3	5	12	9	14	7

Table II. Cancer type.

Cancer type	Respiratory	Brain	Urinary	Gynaecological	Breast	Digestive	Other
Whole sample	24	3	7	16	13	31	6
Control group	12	0	5	7	6	17	3
Study group	12	3	2	9	7	14	3

Table III. Pain characteristics.

Type of pain	Somatic	visceral	neuropathic
• Whole sample	43	47	10
• Control group	21	24	5
• Study group	22	23	5
Intensity of pain	Moderate	Severe	
• Whole sample	65	35	
• Control group	32	18	
• Study group	33	17	

Table IV. Distribution of patients in accordance with medication received for pain.

Drug administrated	Tramadol	Morphine	Differences between study and control group
• Whole sample	62	38	
• Control group	33	17	Not significant
• Study group	29	21	Not significant

Table V. Distribution of patients on tramadol hydrochloride and morphine, according to the frequency of administration.

Frequency of Administration	2 times per day	3 times per day	4 times per day	6 times per day	Differences between study and control group
Tramadol hydrochloride					
Whole sample	8 (13%)	36 (58%)	18 (29%)	0 (0%)	
Control group	4	21	8	0	Not significant
Study group	4	15	10	0	Not significant
Morphine					
Whole sample	3 (8%)	14 (37%)	19 (50%)	2 (5%)	
Control group	1	8	7	1	Not significant
Study group	2	6	12	1	Not significant

Table VI. Distribution of patients that presented local complications in relation to the type of complication.

Type of local complication	INDURATION	REDNESS	BLEEDING	TOTAL
• Whole sample	29 (56%)	17 (33%)	6 (11%)	52 (100%)
• Control group	20	15	5	40
• Study group	9	2	1	12

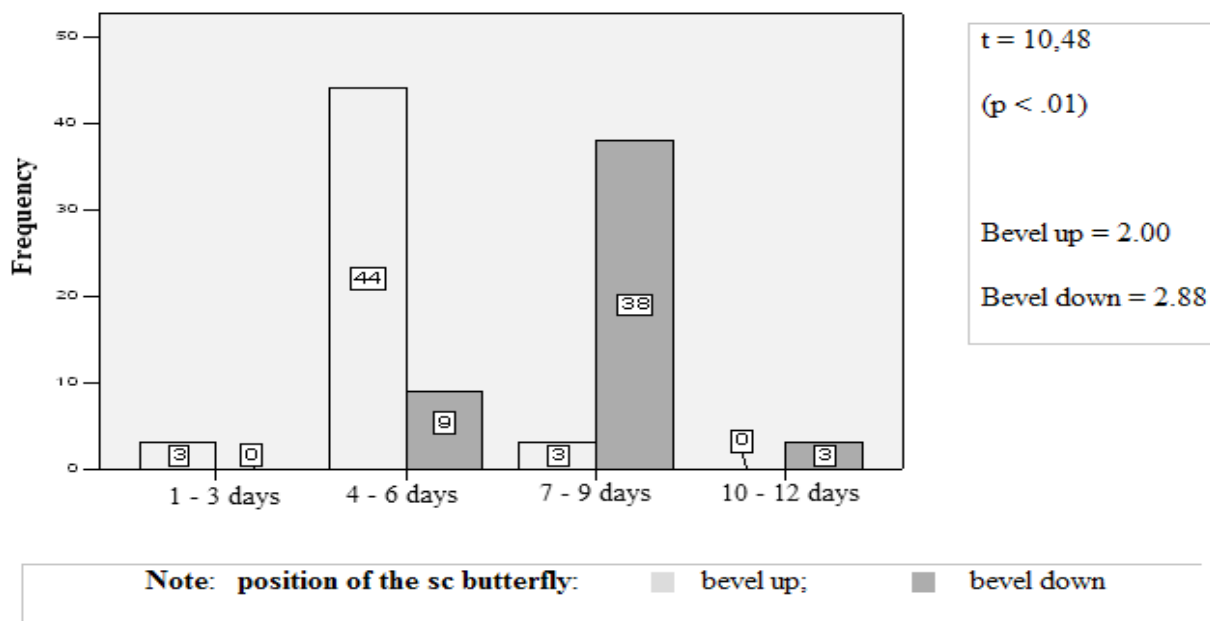


Figure 1. Differences in the sc butterfly resistance at the place of insertion according to the way of positioning the needle bevel – up or down.

Table VII. Distribution of cancer patients according to resistance time for maintaining the sc butterfly at the insertion place.

	1-3 days	4-6 days	7-9 days	10-12 days	TOTAL
Length of time for maintaining the sc butterfly	3 (3%)	53 (53%)	41 (41%)	3 (3%)	100 (100%)

Discussion

The development of practical research studies that aim at improving current nursing techniques by translating research findings into practice has become a focus of many interdisciplinary studies concerning the care of cancer patients. These modalities of care aim at improving the quality and consistency of nursing decision-making, particularly for cancer patients who experience pain. Our major finding concerning the nursing practice is related to the positioning of the butterfly, the needle with the bevel down. This placement position is associated with a longer resistance in time at the site of insertion and causes less local complications compared to the sc butterflies positioned with the bevel up. These findings are a challenge for the actual practice of placing the butterfly with the bevel up.

A limitation of our study is the fact that we did not study the correlation between complications, position of butterfly and the expertise of the nurses carrying out the procedure. A previous Canadian study [17] suggests that the rate of local side effects seems to have decreased over time as the team's expertise in the use of intermittent subcutaneous opioid delivery increased. We did not measure the expertise of the nurses inserting the butterfly and this could be the one limitation factor that we have not taken into consideration.

The most encountered complication was local induration. In contrast with other previous data [18], no site infections and accidental needle pulling were evidenced.

Because primary health care is underdeveloped in Romania [19] there is a low number of district nurses and professional care-takers for home care services. In Romania, home-based palliative care services rely heavily on the input and involvement of the family in the care of patients. In our study, after the butterfly was placed by a hospice nurse the family was taught to administer the medication through the butterfly. Although we provided some training for family members we had no control over the subsequent process. That said, data concerning the duration of the butterfly at the site of insertion were comparable with data from other studies that show a 6.5 days to eight-day overall duration of the sites for intermittent infusions and for continuous infusions of opioids (seven days) [20].

This is a confirmation that administration of pain medication via subcutaneously butterfly by family members is safe practice.

In our study, the most frequent injectable opioid

administered to cancer patients with pain was tramadol hydrochloride. This can be explained by the fact that 65% of the patients included in our study had moderate pain and tramadol is a mild opioid adequate to treat moderate pain. Another explanation is the regulation concerning prescribing procedures for opioids: tramadol is not a scheduled drug in Romania, it is available on normal prescription and physicians are less reluctant to prescribe it. This practice is different from other countries where the most frequently used opioid was hydromorphone, which has also been reported to be well tolerated when used subcutaneously, both as continuous and intermittent infusion [21,22] Fudin, 2000). We do not have available in Romania injectable oxycodone and methadone, which are also reported to be used and well tolerated in subcutaneous administration.

The most encountered frequency of administration was three times per day for tramadol hydrochloride and four times per day for morphine. As the rate or frequency of the rate of administration of sc injectable opioids increases, the chances of local complications occurrence also increase. However, our data also showed administration of tramadol twice a day and of morphine twice, three times or four times a day. This is not standard practice for good pain management in Romania unless there is a degree of kidney failure. It was not the purpose of our study to look at the prescribing patterns; we have not recorded parameters concerning the renal function for the patients in our study, therefore we cannot judge the appropriateness of the prescribing patterns in this study.

Conclusion

Practical research studies are needed to examine and improve current nursing techniques and strategies that are employed in everyday clinical practice. The article challenges the standard nursing practice regarding the insertion of the subcutaneous butterfly with the bevel up. According to our findings the position of the needle with the bevel down ensures a better resistance of the subcutaneous butterfly and fewer side effects. The results of this pilot study need to be proved in a larger study and with better observation given to potential limitation factors such as the number of administrations, types of drugs, nutrition status of the patient, and experience of the nurses performing the procedure.

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