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POST-ANAESTHETIC DENTAL EXTRACTION ANALGESIA: A COMPARISON OF PARACETAMOL, CODEINE, CAFFEINE (SOLPADEINE) AND DIFLUNISAL (DOLOBID)

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Summary. This open, single dose trial compared the analgesic effect of Solpadeine and diflunisal in patients having dental extractions under general anaesthesia. Both drugs were equally efficacious in their effectiveness as an analgesic and although there were no statistical differences in their rate of onset of action, Solpadeine achieved efficacy faster than diflunisal.

Introduction

General anaesthesia for dental extraction where the patient is admitted, operated upon and discharged within a few hours remains popular as a day procedure.

This open, single dose trial aimed to compare the effectiveness, speed of onset, and tolerance of Solpadeine which contains paracetamol 500 mg, codeine phosphate 8 mg and caffeine 30 mg in an effervescent base and diflunisal 250 mg (Dolobid).

The main component of Solpadeine, paracetamol, has been in clinical use since 1956. It is an effective analgesic against pain of moderate intensity such as lumbago, headache and dysmenorrhoea (Woodbury, 1975). While paracetamol and salicylic acid (aspirin) are equally efficacious in their analgesic and antipyretic activity, paracetamol is relatively free from gastric irritation.

Diflunisal is a difluorophenyl derivative of salicylic acid and has analgesic and antipyretic actions. Diflunisal is claimed to be more potent and longer acting than aspirin and has been recommended for the relief of pain in dentistry (Wes, 1978).

Method

Only healthy patients, aged between 18 and 70 years, weighing more than 48 and less than 110 kg, with no known idiosyncracy to these analgesics were accepted for admission to the trial. All patients underwent dental extractions.

All information and subsequent data was noted on a set of cards and stored within an envelope to which was affixed the patient's trial number.

Each patient was interviewed and their cooperation obtained. The 'pain thermometer' (Fig. 1), which is an eleven point scale numbered 0 to 10 (zero being equivalent to no pain at all, ten representing the worst pain imaginable) was demonstrated to each patient before their treatment. No premedication was given and patients were anaesthetised in the supine position. Anaesthesia was induced intravenously with either Althesin or methohexitone (Brietal) and was maintained with nitrous oxide, oxygen and halothane delivered via a Penlon modified Goldman

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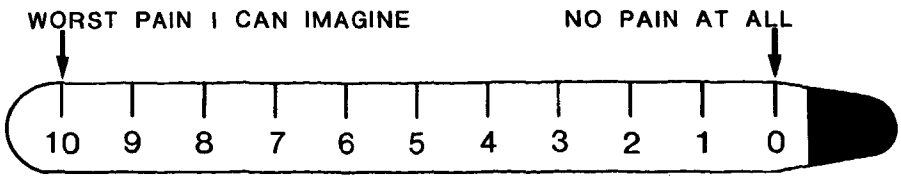

FIG. 1. Pain thermometer.

mask. The anaesthetic and surgical durations were noted and the operation severity and blood loss in each patient were categorised as slight, moderate or severe according to the observations of the dental surgeons.

On recovery of consciousness, when the patient could respond coherently to his name, the pain thermometer was presented and an assessment of the level of pain was recorded. Patients with no pain at this time were excluded.

All other patients received, with a small volume of water, two tablets of either Solpadeine or diflunisal, prescribed according to a randomisation list which had been determined before the trial began. Each patient assessed their level of pain with respect to the thermometer a half, one, one and a half, two and three hours after the tablets were administered. A note was made whether additional analgesia was requested at these times, together with details of the extra treatment when given. After one hour, each patient was asked to compare their pain with that experienced at the time of receiving the initial dose in the following terms; gone, much improved, slightly improved, the same and worse.

At the time of discharge each patient was asked how the particular drug suited them and also to make an assessment of the overall pain relief in respect to the following categories, that is, complete, moderate but incomplete, inadequate and no relief. All patients who had left before the three hours had elapsed were given a stamped addressed envelope to return the completed cards on which the residual information was recorded.

Results

Of the 86 patients whose details were accepted for analysis, 43 (14 male and 29 female) received Solpadeine and an equal number with the same sex distribution received diflunisal (Table I). The groups were similarly matched for age (Table II) and weight (Table III). In respect to operative severity and blood loss, there were no significant differences between each group (Tables IV and V), although a greater frequency of moderate and severe gradings was found in the Solpadeine group.

The mean values of the patients' initial assessment of pain were estimated (Table VI). The improvement in pain relief experienced by each patient after treatment by

Table I
Distribution of male and female patients in the treatment groups

	Sex		
Analgesic	Male	Female	Total
Solpadeine	14	29	43
Diflunisal	14	29	43
Combined	28	58	86

Table II
Distribution of ages and mean ages of patients of both treatment groups

Sex	Analgesic	Age (years) 18–	20–	30–	40–	50–	Total	Mean Age
Male	Solpadeine	0	7	4	1	2	14	32.0
	Diflunisal	3	4	4	3	0	14	30.7
Female	Solpadeine	5	11	8	2	3	29	30.3
	Diflunisal	5	13	7	1	3	29	28.6
Combined	Solpadeine	5	18	12	3	5	43	30.8
	Diflunisal	8	17	11	4	3	43	29.3

Table III
Distribution of weights and mean weight of patients of both treatment groups

Sex	Analgesic	48–	50–	60–	70–	80–	90–	100–	Total	Mean Weight
Male	Solpadeine	0	1	3	8	0	2	0	14	73.4
	Diflunisal	0	1	4	3	4	2	0	14	75.6
Female	Solpadeine	2	15	6	4	2	0	0	29	60.2
	Diflunisal	2	17	6	1	0	2	1	29	61.1

Table IV
Distribution of operative severity as observed by the operator in the treatment groups

Analgesic	Severity of Operation Slight	Moderate	Severe	Total
Solpadeine	16	16	11	43
Diflunisal	24	12	7	43
Combined	40	28	18	86

Table V
Blood loss for each patient in the treatment groups as observed by the operator

Analgesic	Slight	Moderate	Severe	Total
Solpadeine	24	18	1	43
Diflunisal	32	11	0	43
Combined	56	29	1	86

Table VI
Initial mean pain score and distributions of mean improvement as assessed by patients in the treatment groups

Analgesic	Initial mean score	Mean improvement in pain after (hr)				
		½	1	1½	2	3
Solpadeine	4.53	−2.07	−2.26	−2.45	−2.62	−2.64
Diflunisal	4.16	−1.12	−1.88	−2.05	−2.69	−2.95
Significance	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.

one of the two analgesics was assessed by subtracting their pain thermometer scores after a half, one, one and a half, two and three hours from the initial rating of pain immediately after the extraction. A Mann Whitney U test was then used to test the difference in pain relief afforded to those patients who received Solpadeine and for those who received diflunisal. Although there were notable differences in initial pain scores (4.53 for Solpadeine and 4.16 for diflunisal) there was a marked numerical reduction in pain scores for Solpadeine over diflunisal within the first half hour (Table VI). The analgesic superiority is retained by Solpadeine for the first one and a half hours when both groups attain a similar level of pain experience (Table VI). Furthermore, mean reduction of pain scores within each group reach numerical equivalence after two hours, 2.62 for Solpadeine and 2.69 for diflunisal (Table VI). When initial mean scores and mean improvements in pain were calculated separately for each sex, there were no statistically significant differences between the groups at any time.

At one hour after administration of the drug, when each patient was asked to categorise his pain relief in reference to the pain experienced immediately after operation, 21 patients who had taken Solpadeine against 17 patients who had taken diflunisal experienced complete relief or who were much improved (Table VII). Only four patients, three Solpadeine and one diflunisal felt their pain was worse. Altogether 53 (28 Solpadeine and 25 diflunisal) patients experienced at least some improvement (Table VII).

On discharge, each patient was asked to assess their overall pain relief. These assessments were made after differing time periods from medication had elapsed.

Table VII
Distribution of patient responses in both treatment groups when after one hour being asked to compare their current pain with that experienced immediately after operation

Sex	Analgesic	Comparison of pain after one hour						
		Gone	Much improved	Slightly improved	The same	Worse	n.s.	Total
Male	Solpadeine	2	6	2	4	0	0	14
	Diflunisal	3	1	3	6	1	0	14
Female	Solpadeine	3	10	5	8	3	0	29
	Diflunisal	5	8	5	10	0	1	29
Combined	Solpadeine	5	16	7	12	3	0	43
	Diflunisal	8	9	8	16	1	1	43

Table VIII
Assessment of pain relief at the time of discharge by each patient in the treatment groups

		Pain Relief					
Sex	Analgesic	Complete	Moderate but incomplete	Inadequate	None	n.s.	Total
Male	Solpadeine	2	12	0	0	0	14
	Diflunisal	5	6	2	0	1	14
Female	Solpadeine	6	21	0	1	1	29
	Diflunisal	8	17	2	2	0	29
Combined	Solpadeine	8	33	0	1	1	43
	Diflunisal	13	23	4	2	1	43

Table IX
Number of patients requiring extra analgesia at times when pain was assessed

	Number of patients requiring extra analgesia after (hr)					
Analgesic	½	1	1½	2	3	Total*
Solpadeine	1	1	2	2	7	12
Diflunisal	2	3	1	1	0	5
Combined	3	4	3	3	7	17

*There were patients in both groups who required extra analgesia on more than one occasion.

Only 14 patients (two Solpadeine and 12 diflunisal) felt their pain was nil or inadequate. On the whole, both groups experienced relief from their pain, but there were no significant differences between the two analgesics in terms of effectiveness on discharge (Table VIII). Of the 17 patients who required additional analgesia, 12 belonged to the Solpadeine group. Six of these patients however, did not require medication until three hours after the first dose had elapsed and it must be assumed that the first dose gave adequate analgesia albeit short lived. Only one patient in the Solpadeine group of 12 required a second additional dose. Of the five patients who required further analgesia in the diflunisal group, two received a second additional dose (Table IX).

Only four patients when asked how the drug suited them complained of side effects; two patients in the Solpadeine group and one patient in the diflunisal group complained of nausea. A further patient in the Solpadeine group complained that the medication had an unpleasant taste.

Discussion

Paracetamol currently enjoys equal popularity as an over-the-counter analgesic with aspirin. Both aspirin and paracetamol have been shown to be equally efficacious and superior to placebo in their ability to relieve pain of mild or moderate severity (Wallenstein *et al.*, 1954). Inevitably in an attempt to improve the efficacy of paracetamol over aspirin, paracetamol has become an ingredient of compound

analgesics with centrally acting drugs such as codeine, dihydrocodeine, dextropropoxyphene and pentazocine. Similarly, the addition of an effervescent substance such as sorbitol has been shown to increase the rate of absorption of analgesics taken orally. While there are many factors affecting the appreciation of pain and there is a wide subjective difference between individuals, a rapid onset of pain relief is a particularly desirable analgesic characteristic in the relief of post-extraction pain. This study supports what would have been expected i.e. Solpadeine predissolved in a small amount of water is superior in producing a more rapid onset of analgesia within the first half hour than from an equivalent amount of undissolved diflunisal. In fact it is only after two hours that diflunisal attains a similar analgesic efficacy to Solpadeine. Furthermore if it were possible to exclude those patients who had a history of poor analgesic response to paracetamol, this result may have been further exaggerated in favour of Solpadeine. Approximately 25 per cent of the general population are poor absorbers of paracetamol (Gwilt *et al.*, 1963). The addition of sorbitol to produce effervescent predissolved paracetamol reduces the incidence significantly, and leaves only 10 per cent who would absorb Solpadeine poorly. Other factors which might delay gastric emptying and thus delay absorption of paracetamol in the small intestine, such as food, narcotics or premedicants were not involved under the conditions of this study.

Diflunisal is a single dose study has been shown to be significantly more effective than placebo and of similar efficacy to aspirin in the relief of post-operative pain (DeVroey, 1978). In a comparative placebo controlled multidose study of analgesia following surgical removal of impacted lower wisdom teeth, diflunisal was shown to be statistically superior to placebo in 86 per cent of patients (Wes, 1978). A multiclinic study indicated significant relief in 84 per cent of patients following a single dose of diflunisal (van Winczum, 1977). Our study indicated that Solpadeine is superior to diflunisal in its ability to produce a rapid onset of analgesia and confirms that both Solpadeine and diflunisal become equally efficacious as an effective analgesic after two hours. In no way does it refute or confirm the suggested superiority of diflunisal over conventional analgesics in terms of its prolonged length of action. Although patients were not specifically asked about side effects, they were given an opportunity at the time of discharge to put forward any complaints by being asked how the drugs suited them. Their responses indicated a low incidence of side effects for both drugs and confirms a general tolerance for both of them.

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