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Analgesia in the acute abdomen

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Summary

In a prospective sequential double blind trial 288 patients with acute abdominal pain were given sublingual buprenorphine 200 mcg, sublingual buprenorphine 400 mcg, or placebo. Pain relief was proportional to the number of tablets administered; buprenorphine had no difference in effect compared to placebo. Physical signs altered in proportion to dosage, but this had no effect on clinical diagnosis. We conclude that patients with acute abdominal pain may be given buprenorphine without fear of masking the diagnosis.

Introduction

The use of analgesia to quell acute abdominal pain has long been subject to argument. Many surgeons believe relief of suffering is best procured by accurate diagnosis first, followed by treatment which will include analgesia. However, delay often ensues before an accurate diagnosis is established. During this interval analgesia is withheld, since it is deemed to obscure or alter the physical signs. Is there any data to substantiate this view? Surprisingly, very little; a trial was therefore planned in an attempt to provide a factual basis for discussion.

Patients and methods

All patients admitted to Harrogate District Hospital from July 1983 to July 1984 with acute abdominal pain were eligible for the study. Patients were excluded for five reasons only; children under the age of 16 as buprenorphine is not licenced for use under this age; patients with renal colic as it was considered unethical to give them placebo; patients with no pain on admission, though if they developed pain later they were eligible; patients with no signs, as there would be no change; and patients where it was felt that urgent clinical treatment would have to over-ride any trial considerations, for example leaking aortic aneurysms. The trial protocol was approved by the Hospital Ethical Committee.

Various modes of analgesia were considered. Many patients with acute abdominal pain are nauseated and may be vomiting and oral analgesia is inappropriate. Intramuscular injections can be variable in absorption and injecting placebo may be construed unethical and invasive. Sublingual buprenorphine has none of these objections and was felt appropriate for use.

Trial patients were admitted by the resident surgeon on standard forms widely used elsewhere *(1)*. The patient then received a numbered pre-randomised trial tablet, the contents unknown, ensuring that the trial was double blind. After one hour, the same surgeon re-examined the patient, ascertaining three specific points.

Has the pain changed? The patients were asked whether the pain was better, the same or worse.

Have the abdominal signs changed? Any change in signs on full abdominal re-examination was noted, or 'no change' was specified. The use of an independent assessor to re-examine patients would have introduced observer variation in elicitation of physical signs; re-examination by the same surgeon kept this variation to a minimum.

What is the diagnosis now? Every encouragement was made to enter one diagnosis rather than a differential.

Three sequential trials were performed. Trial I consisted of randomisation to receive buprenorphine 200 mcg or one placebo tablet sublingually. The results were analysed when 125 patients had been entered *(2)*. This study was open to possible criticism that adequate analgesia had not been obtained. Trial II thus consisted of randomisation to buprenorphine 200 mcg×2 or placebo×2 sublingually. This demonstrated a greater placebo effect. Trial III consisted of a further group of patients who received neither active nor placebo tablets, but were followed according to the same protocol.

Results

Over 60% of all acute admissions during the trial period were entered into the trial. Of the remainder, 11% were not acute abdomens, 12% were acute retentions, 4% were renal colic, 3% underage, 5% miscellaneous and 2% abdominal catastrophes. Trial I comprised 125 patients with 9 (7%) not being re-examined, leaving 116 for analysis. In Trial II 143 patients were entered, with 3 (2%) not re-examined, leaving 140 for analysis. All 32 patients in Trial III were available for analysis.

Table I shows the number of patients in each trial receiving buprenorphine and placebo. It shows no significant difference between any of the groups with respect to age, sex, or discharge diagnosis. The latter was a simplified classification into operative pathology (OP), that is acute abdominal conditions needing operation such as appendicitis; pathology (P), acute abdominal conditions not needing urgent operation, for example cholecystitis; or non-specific abdominal pain (NSAP), either by exclusion or proven by negative laparotomy. No side effects worthy of mention were noted with any buprenorphine group; in particular no excess of nausea or vomiting was noted.

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TABLE I *Patient details*

	Total	Av age	Male	Female	Discharge diagnosis OP	P	NSAP
Buprenorphine ×1	59	46.4	25	34	13	17	29
Placebo ×1	57	43.2	29	28	16	15	26
Buprenorphine ×2	75	48.3	32	43	19	21	35
Placebo ×2	65	43.2	32	33	19	16	30
No tablet	32	50.1	15	17	8	9	15

Did the analgesia work? (Table II). Buprenorphine 200 mcg produced pain relief in 22 patients (37%) and placebo also produced pain relief in 23 patients (40%). Doubling the dose increased the analgesic effect, so that 42 patients who received buprenorphine (56%) and 36 who received placebo (55%) now obtained analgesia. In the control series 6 (19%) had spontaneous resolution of pain.

Did the physical signs change? (Table III). In Trial 1 10 patients (8.5%) had a change in physical signs. In only two cases did buprenorphine produce an analgesic effect associated with a change in signs. In Trial II 36 patients (26%) had altered physical signs; in fifteen cases this was associated with pain relief having received buprenorphine. In Trial III 4 patients had changes in physical signs, 2 of them associated with spontaneous relief of pain. In total therefore, 17 patients in the entire study group of 288 (6%) might have had their physical signs altered by an administered analgesic, which represents 17/134 (12%) of those receiving buprenophine.

Of the 50 patients whose signs changed, the majority, 32, were alteration in bowel sounds—a notoriously subjective physical sign. The remaining 18 consisted of alteration in site of tenderness, in most cases a resolution of a large region to a smaller, more precise area.

Did the diagnosis alter? In all three trials, in no case was the diagnosis altered by a change in physical signs. In several cases the correct diagnosis was facilitated, especially in the 18 cases whose site of pain changed. In order to confirm that this failure to change diagnosis did not represent lack of clinical acumen, all cases in Trial I and the majority of cases in Trial II whose signs changed were run on a computer programme for acute abdominal pain *(1)* using the signs before and after the analgesia. The diagnostic probabilities were hardly altered at all, lending strong support to the clinical decisions.

Discussion

Common teaching, based on a classical text *(3)*, strongly advocates withholding analgesia in patients with acute abdominal pain until a diagnosis has been made. Unfortunately, in clinical practice there is often substantial delay before a proven diagnosis is reached. Recent criticisms of this standard teaching deplore this delay in giving analgesia *(4)* and maintain that the pain relief obtained may even help elucidate the diagnosis *(5)*. Data from trials has not been available to support either of these two divergent opinions.

This trial suggests that more patients obtain pain relief if given two tablets sublingually (60%) than if given one tablet (40%). This is still greater than the numbers obtaining pain relief if given no tablet (20%)—a figure supported by other reports *(6, 7)*. However, the contents of the tablet are apparently irrelevant, since placebo fared as well as buprenorphine in producing analgesia.

TABLE II *Did the analgesia work?*

	Pain after 1 hour Better	Same	Worse
Buprenorphine ×1	22 (37%)	35	2
Placebo ×1	23 (40%)	32	2
Buprenorphine ×2	42 (56%)	29	4
Placebo ×2	36 (55%)	23	6
No tablet	6 (19%)	25	1

TABLE III *Did the physical signs change?*

	Pain after 1 hour Better	Same	Worse
Trial I n=10/116			
Buprenorphine ×1	2	1	1
Placebo ×1	4	1	1
Trial II n=36/140			
Buprenorphine ×2	15	2	1
Placebo ×2	13	2	3
Trial III n=4/32			
No tablet	2	1	1

The trial was designed to answer whether physical signs change as a result of analgesia. The answer appears to be yes; in trial II more patients obtained analgesia than in trial I, and more patients had changes in physical signs. This occurred whether the analgesia was due to active buprenorphine or placebo; the argument for drug-induced change in physical signs could not thus be sustained. Only 17 out of all those who received buprenorphine had altered physical signs (12%) compared with 19 controls (12%).

A subsidiary point raised by the trial was whether the effect of analgesia on change in physical signs might be related to the presence or absence of genuine pathology. Careful examination of all subgroups according to analgesic effect, change in signs, and diagnostic grouping failed to reveal any significant differences. This implies that the effect of analgesia on physical signs cannot be used as a diagnostic test.

The final question for discussion was whether the change in physical signs made any difference to the diagnosis. The answer was unequivocally negative. In no case whose signs altered was the diagnosis changed, this was confirmed by retrospective analysis both clinically and by computer. In 4 cases the correct diagnosis was clarified, but in none was it obscured.

We conclude that administering sublingual buprenorphine to patients with acute abdominal pain relieves their pain in over 55% of cases, though placebo is as effective. Physical signs do change, but in an inconstant fashion, and as much with placebo as with active analgesic. Any change in signs that does result does not hamper making the diagnosis, and in a few cases may make it more obvious. Buprenorphine 200 mcg or 400 mcg may safely be given to patients with acute abdominal pain, to relieve that pain without masking the diagnosis.

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