Colonoscopy results are not enhanced by use of magnet endoguide in specialist practice

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ABSTRACT

INTRODUCTION: It is discussed whether the use of a magnetic positioning device (OLYMPUS; UPD (unit of magnetic positioning device)) enhances the success of the colonoscopic procedure. Concern for patient compliance and endoscopic efficiency has been voiced in connection with the implementation of colon cancer screening. UPD has been proposed as a tool for optimization of results and reduction of patient discomfort. In this study, we aimed to qualify the debate by examining the success rate and patient discomfort in an unselected colonoscopy population referred to specialist clinics with experienced investigators. Furthermore, the study assessed the effect of using a UPD.

MATERIAL AND METHODS: A total of 1,068 consecutive patients referred for colonoscopy were enrolled and randomised for investigation with or without use of UPD. The evaluation endpoints were: success rate (coecum visualised, ileal intubation was carried out at the investigator's discretion), duration of procedure, and patient discomfort indicated by the patient as a visual analogue scale score.

RESULTS: No significant differences between the two investigational procedures were demonstrated in relation to the chosen endpoints.

CONCLUSION: UPD is convenient to have, but not a necessity for colonoscopy.

FUNDING: The study was supported by the Danish Association of Medical Specialists.

TRIAL REGISTRATION: The study was approved by the Danish Data Protection Agency, journal no. 2009-41-3716, the National Ethics Committee, journal no.: H-1-2009-80, and registered with ClinicalTrials.gov., protocol no: NCT01055782.

Since the introduction of a magnetic positioning device for endoscopy [1], its significance for colonoscopy has been widely discussed, and several articles concerning its effect on learning curves, success rates, safety and patient comfort have been published [2-4].

However, the impact on colonoscopies carried out in a specialist practice with a highly experienced staff and a large amount of open access patients has not previously been reported [5].

MATERIAL AND METHODS

Patients

All patients referred to the two clinical units for colonoscopy were invited to participate in the study, acknowledging the exclusion criteria. Theoretical power calculations were non-applicable in this study, as it was designed to run for a two-year period during which we expected to include 1,000 patients. If no effect could be established within this time or volume frame, the equipment would be deemed of no importance in a basic clinical context.

In 16 months, 1,068 patients were referred for colonoscopy and 1,004 were found eligible and entered the study.

Reasons for exclusion are shown in **Figure 1**.

Randomisation

All patients were given verbal and written information and signed an informed consent document.

The patients were randomised for investigation with our standard equipment, with or without the endoguide system (unit of magnetic positioning device, UPD) connected. The investigational procedure – including the bowel cleansing procedure (see below) – was not otherwise altered. The randomisation was carried out as allocation by date.

The UPD alternation between the two clinics was decided and handled by the company administering and transporting the UPD. UPD alternation on the one hand and scheduling of patient appointments by the clinics' secretaries on the other were carried out independently.

That's the question.
Illustration by
Kristoffer Kjærgaard Hendel.

ORIGINAL ARTICLE

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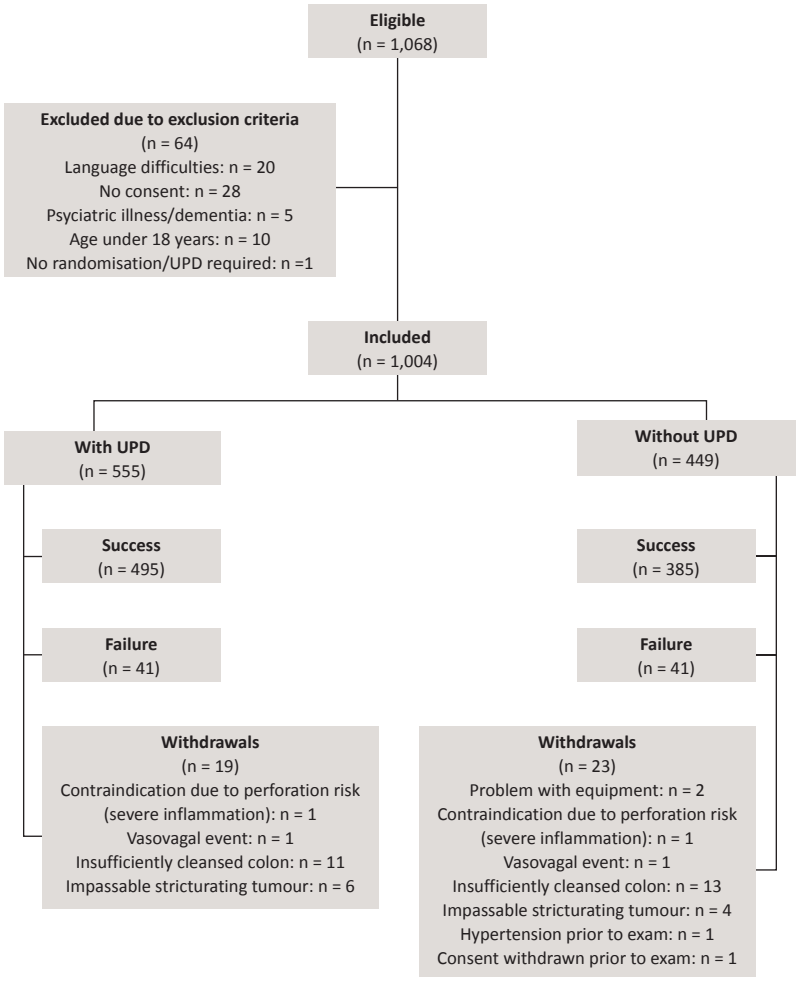
FIGURE 1

Flow chart.



UPD = unit of magnetic positioning device.

Equipment

The standard endoscopy equipment was supplemented with a portable magnetic endoscope imaging unit (Olympus ScopeGuide system, UPD) [6].

Colonoscopy

Bowel preparation: PICOPREP was routinely used for bowel cleansing. The over-the-counter (OTC) medication was distributed to the patient by the clinic free of charge, and the patient received written and verbal instructions on how to use it properly.

Sedation was optional and patient-decided.

After the procedure, the patient was invited to indicate discomfort during the procedure as a visual analogue scale (VAS) (VAS 1) score 0-10, 0 being no discomfort at all, 10 being severe discomfort (painful). The patient received a second, identical VAS form (VAS 2) to fill in at home the day after the colonoscopy and sent in a prepaid envelope to the clinic. The patient was carefully instructed (before the procedure) to record the discomfort of the investigation performed the previous day.

In a subgroup of patients, the endoscopy assistant also filled in a VAS to give a staff impression of how the patient reacted to the investigation (VAS 3).

The concept that the endoscopic procedure would be the same whether the patient participated in the study or not was thoroughly described to the patient, and written informed consent for VAS score estimation was obtained.

Statistical analyses

First, VAS scores and intubation time were compared between the UPD and the non-UPD group. As the variables were not normally distributed, we used the non-parametric Wilcoxon rank sum test and the Wilcoxon signed rank test for paired observations. The proportion of successful endoscopy for each physician as well as the total proportion were calculated and compared between the two groups by either the χ^2-test or Fisher's exact test, whichever appropriate.

Furthermore, we performed multivariate regression analyses on three different outcome variables. An ordinary logistic regression analysis was carried out on the binary outcome measuring success or failure. As the assumptions of a linear regression model were not fulfilled for the two continuous outcome measures, VAS and intubation time, we grouped the observations according to the percentiles of their distribution and performed ordinal logistic regression analyses. Gender, age and UPD were included as explanatory variables in all regression analyses. As age was not a linear predictor in two of the three regression analyses, we included this variable as categorical in all three regressions defining age groups according to the age distribution. We estimated robust standard errors in order to account for clustering of patients.

All analyses were performed using the statistical software Stata version 11 (Stata Corp LP, College Station, TX) and the level of significance was set at 5%.

Trial registration: The study was approved by the Danish Data Protection Agency (journal no. 2009-41-3716), by the National Ethics Committee (journal no.: H-1-2009-80) and registered with ClinicalTrials.gov (protocol no: NCT01055782).

RESULTS

A total of 1,004 patients out of 1,068 were found eligible to enter the study according to the protocol (Figure 1). Distribution of patients between the clinics, patient de-

TABLE 1

Patient demography and success rates. Patient demography and distribution of UPD procedures. Withdrawals were excluded.

	Clinic A	Clinic B	All
Age, years, median (range)	60 (22-86)	56 (18-91)	58 (18-91)
Gender, n (%)			
Male	235 (49.0)	186 (38.6)	421 (43.8)
Female	245 (51.0)	296 (61.4)	541 (56.2)
Total	480 (100.0)	482 (100.0)	962 (100.0)
UPD, n (%)			
With	279 (56.8)	276 (53.8)	555 (55.3)
Without	212 (43.2)	237 (46.2)	449 (44.7)
Total	491 (100.0)	513 (100.0)	1,004 (100.0)
Colonoscopy, n (%)			
With UPD	190 (56.2)	55 (56.7)	245 (56.3)
Without UPD	148 (43.8)	42 (43.3)	190 (43.7)
Total	338 (74.3)	97 (22.8)	435 (49.4)
Ileo-colonoscopy, n (%)			
With UPD	69 (59.0)	181 (55.2)	250 (56.2)
Without UPD	48 (41.0)	147 (44.8)	195 (43.8)
Total	117 (25.7)	328 (77.2)	445 (50.6)

UPD = unit of magnetic positioning device.

TABLE 2

Success proportion for UPD compared to non-UPD.

	UPD		Non-UPD		
	n	success-%	n	success-%	p-value[a]
Physician 1	235	95.7	168	95.2	0.808
Physician 2	38	89.5	39	92.3	0.711
Physician 3	55	96.4	37	91.9	0.388
Physician 4	123	93.5	96	85.4	0.048
Physician 5	85	80	56	76.8	0.648
Physician 6	0	–	30	100.0	–
Total	536	92.4	426	90.4	0.276

UPD = unit of magnetic positioning device.
a) χ^2-test or Fisher's exact test, whichever appropriate.

mography, distribution of use versus non-use of UPD, and success rates for the clinics as well as for the individual endoscopists are shown in **Table 1** and **Table 2**.

In all, 126 patients were investigated without sedation. Also in this subgroup, the use of UPD had no significant influence.

A total of 42 of 1,004 colonoscopies were withdrawn for reasons that were not endoscopist-related (Figure 1).

Success rate

A total of 555 patients were investigated with UPD; 19 patients had to be withdrawn prior to or during the endoscopy. In all, 41 colonoscopies were not completed (failures) and 426 patients were investigated without

TABLE 3

Statistical evaluation of intubation time. Difference in intubation time – UPD compared with non-UPD.[a]

	UPD			Non-UPD			
		intubation time, min.			intubation time, min.		
Intubation	n	median	range	n	median	range	p-value
Success	493	10	4-50	378	10	3-55	0.826
Failure	25	10	5-40	27	10	5-30	0.992

UPD = unit of magnetic positioning device.
a) Medians were compared using Wilcoxon rank sum test due to non-normally distributed observations.

TABLE 4

Statistical evaluation of VAS. Difference in VAS score – UPD compared with non-UPD.[a]

	UPD			Non-UPD			
		VAS score			VAS score		
	n	median	range	n	median	range	p-value
VAS 1[b]	525	3.3	0-10	411	3.6	0-10	0.260
VAS 2[c]	493	2.9	0-10	391	2.6	0-10	0.818
VAS 3[d]	239	2.7	0-10	193	3.2	0-10	0.144

UDP = unit of magnetic positioning device; VAS = visual analogue scale.
a) Medians were compared using Wilcoxon rank sum test due to non-normally distributed observations.
b) VAS score by the patient immediately after termination of the colonoscopy.
c) VAS score by the patient on the day after colonoscopy.
d) VAS score by the assistant immediately after termination of the colonoscopy.

UPD. Furthermore, 23 patients had to be withdrawn prior to or during the endoscopy, and 41 colonoscopies were not completed (failures). Patient demography and diagnostic pattern in failures did not differ from the diagnostic referral pattern.

The UPD success rate was 92.4%, whereas the non-UDP success rate was 90.4%. This difference is statistically insignificant as were the success rates calculated for the individual endoscopists (Table 2). The proportion of ileal intubation is also presented in Table 1.

Visual analogue scale score

A total of 936 (93%) patients completed a VAS 1 form, 884 (88%) patients completed a VAS 2, and 432 (43%) patients completed a VAS 3 form. No significant differences allocated to the use of UPD were demonstrated. In both groups, VAS 2, however, was significantly lower than the corresponding VAS 1 (**Table 3**, **Table 4** and **Table 5**).

Duration of procedure: The duration of intubation time (minutes) was compared with and without UPD and no significant differences were demonstrated (Table 3).

In **Table 6** multivariate analyses for success rate, VAS-score and intubation time show no significant difference between UPD and non-UPD.

Adverse events: One patient was hospitalised (self-admittance) due to abdominal pain and discharged without intervention after spontaneous relief.

TABLE 5

Statistical evaluation of VAS. Difference in VAS score – VAS 1 compared with VAS 2.[a]

	VAS 1			VAS 2			
		score			score		
	n	median	range	n	median	range	p-value
UPD	525	3.3	0-10	493	2.9	0.10	< 0.001
Non-UPD	411	3.6	0-10	391	2.6	0.10	< 0.001

UPD = unit of magnetic positioning device; VAS = visual analogue scale.
a) Medians were compared using Wilcoxon signed rank test due to non-normally distributed, but paired observations.

DISCUSSION

Quality assessment, quality control and accreditation are currently important issues.

In this context, access to specialised equipment is very much in play. Success rates and patient safety are punch words when planning colon cancer screening programmes. Hence, it was suggested that access to a positioning device during colonoscopy may increase patient safety and procedure efficacy.

However, the use of a UPD has previously been shown to favour less experienced colonoscopists and to be of no importance for highly experienced colonoscopists [7-9].

Our study confirms that access to a UPD does not significantly enhance the performance of experienced endoscopists in specialist clinics.

Although the statistics show no evidence of beneficial effects of the UPD, either in success rate or in patient comfort (VAS score), all investigators but one preferred working with it.

In the present study, we confirmed that a specialised stand-alone unit not located within a hospital is sufficiently equipped and has an adequate intake of colonoscopies per endoscopist to participate in colon cancer screening.

One of the participating clinics was staffed with surgeons, the other with gastroenterologists (internists). This is to some extent reflected in the referral diagnoses and, consequently, in the endoscopic diagnoses. The attitude towards ileocaecal valve intubation also differs between surgeons and gastroenterologists, but the reluctance of the former towards ileum intubation changed to acceptance during the study, which obviously brought on an increasing success rate of ileocolonoscopy, but as attempted ileal intubation was not mandatory, ileal intubation cannot be included in the statistical evaluation.

We found no individual correlation between the number of colonoscopies, success rate and VAS score in our study, but as a rule, all of the participating endoscopists completed more than 200 colonoscopies annually. This is in accordance with other publications [10-12].

However, it seems to be of great importance to constantly monitor one's success rate. The single investigator (no. 5) who had a significantly lower success rate than the other investigators had previously demonstrated a much higher success rate, but obviously lost momentum during the study, while all other investigators were performing consistently.

Previously reported success rates vary widely [7-9, 11-13].

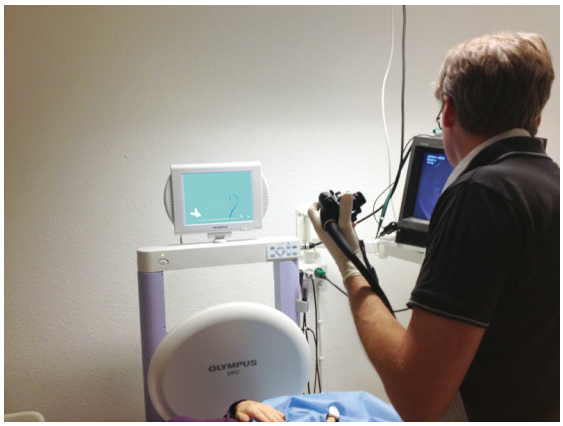
It is not simple to compare results. The methods used for recording of success rate and for determination of patient discomfort differ considerably between studies. Some papers record calls for assistance during a colonoscopy, other papers deal with a "crude" patient population, as we do, and others with a highly cleansed patient material.

Dechêne et al [9] looked into different components of patient discomfort with emphasis on turns of the patient and abdominal compression and found the latter to be significant for patient comfort and dependent on the use of a magnet endoguide. In our patient material, we recorded only intubation time and patient discomfort and found no difference between the two patient groups.

The variety of diagnoses in patient populations from various studies and from hospital and practice settings may differ, although probably not as much as may be expected. There are no differences in diagnoses when we compare failed and successful endoscopies.

Our scope was primarily to compare the efficacy of having access to a UPD in relation to success rate and patient comfort. In addition, we show that a specialist practice dealing with a "crude" population of patients performs with a perfectly acceptable quality concerning success rate and patient comfort irrespective of use of UPD.

Furthermore, we confirm an old prejudice as we



Colonoscopy with magnet endoguide connected.

TABLE 6

Logistic regression on failure, VAS score and intubation time. Robust standard errors estimated as the observations were clustered within physician.

	Failure[a]			VAS score[b]			Intubation time[c]		
	OR	95% CI	p-value	coeff.[d]	95% CI	p-value	coeff.[d]	95% CI	p-value
Gender									
Male	0.34	0.22-0.53	< 0.001	–0.73	–0.94-–0.53	< 0.001	-0.49	–0.68-–0.30	< 0.001
Female	Ref.			Ref.	–	–	Ref.	–	–
Age, years									
< 45	Ref.	–	–	Ref.	–	–	Ref.	–	–
45-54	0.37	0.15-0.88	0.025	–0.16	–0.51-0.19	0.376	0.48	0.17-0.78	0.002
55-64	0.51	0.26-1.00	0.051	–0.44	–0.60-–0.27	< 0.001	0.81	0.58-1.05	< 0.001
≥ 65	0.70	0.51-0.95	0.023	–0.52	–0.63-–0.41	< 0.001	0.72	0.40-1.04	< 0.001
UPD									
Yes	0.80	0.53-1.23	0.310	–0.09	–0.40-0.23	0.598	0.06	–0.21-0.34	0.652
No	Ref.			Ref.	–	–	Ref.	–	–
Intubation time, minutes									
≤ 10	Ref.	–	–	–	–	–	–	–	–
> 10	0.27	0.08-0.88	0.029	–	–	–	–	–	–

CI = confidence interval; OR = odds ratio; VAS = visual analogue scale.
a) An odds ratio below one indicates lower odds of failure compared with the reference group. An OR above one indicates higher odds of failure compared with the reference group.
b) VAS score divided into the categories: < 1.5, 1.5-3.5, 3.5-6.5, > 6.5.
c) Successful examinations only. Intubation time divided into the categories: < 7, 7-9, 10-14, ≥ 15 min.
d) A negative coefficient indicates greater chance of a short intubation time compared with the reference group. A positive coefficient indicates greater risk of long intubation time compared with the reference group.

prove age and gender to be very strong discriminators for a successful colonoscopy (Table 6) [10].

CONCLUSION

A positioning device is convenient to have, but not a necessity. These devices are "nice to have" rather than "need to have".

However, all participating specialists except one preferred working with the UPD, and it cannot be outruled that there is a small and in this study insignificant tendency that the UDP makes difficult colonoscopies easier to complete.

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