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|------------------------------|---|---------|
| <i>Commentary</i> | Exploration of clinical pharmacist management system and working model in China Man Zhu, Dai-Hong Guo, Gui-Yang Liu, Fei Pei, Bo Wang, Dong-Xiao Wang, Wei-Lan Wang and Cui-Li Huang | 411–415 |
| <i>Case Report</i> | Hypersensitivity to tranexamic acid: a wide spectrum of adverse reactions Selene Imbesi, Eustachio Nettis, Paola L. Minciullo, Elisabetta Di Leo, Antonella Saija, Angelo Vacca and Sebastiano Gangemi | 416–419 |
| <i>Short Research Report</i> | A randomized cross-over study to evaluate the swallow-enhancing and taste-masking properties of a novel coating for oral tablets Virgilijus Uloza, Ingrida Uloziene and Egle Gradauskiene | 420–423 |
| <i>Research Articles</i> | Knowledge of medicine outlets' staff and their practices for prevention and management of malaria in Ghana Kwame O. Buabeng, Lloyd K. Matowe, Felicity Smith, Mahama Duwiejua and Hannes Enlund | 424–431 |
| | Factorial invariance of a questionnaire assessing medication beliefs in Japanese non-adherent groups Naomi Iihara, Kiyo Suzuki, Yuji Kurosaki, Shushi Morita and Keizo Hori | 432–439 |
| | An evaluation of consumers' knowledge, perceptions and attitudes regarding generic medicines in Auckland Zaheer-Ud-Din Babar, Joanna Stewart, Shiwangni Reddy, Woroud Alzaher, Prateeka Vareed, Nineweh Yacoub, Bandhana Dhroptee and Anne Rew | 440–448 |
| | Discrepancies between sources providing the medication histories of acutely hospitalised patients Louise Lindved Karkov, Simon Schytte-Hansen and Lotte S. Haugbølle | 449–454 |
| | Counselling behaviour and content in a pharmaceutical care service in Swedish community pharmacies Anna T. Montgomery, Åsa Kettis Lindblad, Pernilla Eddby, Emelie Söderlund, Mary P. Tully and Sofia Källemark Sporrang | 455–463 |
| | Applicability of the REALM health literacy test to an English second-language South African population Ros Dowse, Lebo Lecoko and Martina S. Ehlers | 464–471 |
| | Provision of pharmaceutical care by community pharmacists: a comparison across Europe Carmel M. Hughes, Ahmed F. Hawwa, Claire Scullin, Claire Anderson, Cecilia B. Bernsten, Ingunn Björnsdóttir, Maria A. Cordina, Filipa Alves da Costa, Isabelle De Wulf, Patrick Eichenberger, Veerle Foulon, Martin C. Henman, Kurt E. Hersberger, Marion A. Schaefer, Birthe Søndergaard, Mary P. Tully, Tommy Westerlund and James C. McElnay | 472–487 |

A randomized cross-over study to evaluate the swallow-enhancing and taste-masking properties of a novel coating for oral tablets

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Received: 23 December 2009 / Accepted: 17 May 2010 / Published online: 4 June 2010
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Abstract *Objective* To explore the swallowing-enhancing and taste-masking effects of MedCoat, a new disposable device used to apply a coating to tablets just before oral administration. *Setting* Kaunas Medical University Hospital in Lithuania. *Method* The study was performed as a randomized cross-over study. In total 41 subjects (20 male and 21 female) were enrolled in the study. Subjects were healthy volunteers who at least sometimes experience difficulties swallowing tablets. Subjects were asked to swallow placebo tablets uncoated and coated with MedCoat in a randomized order, and indicate their preferences. Subjects were also asked to evaluate the taste-masking properties of MedCoat. *Results* Of the 41 subjects, 40 (97.6%) found it less difficult to swallow non-flavoured placebo tablets coated with MedCoat compared to identical uncoated tablets. Forty subjects (97.6%) found it less difficult to swallow divided non-flavoured placebo tablets coated with MedCoat compared to identical uncoated divided tablets. All 41 subjects (100.0%) found it less difficult to swallow bitter flavoured placebo tablets coated with MedCoat compared to identical uncoated tablets. All 41 (100.0%) of the subjects stated that MedCoat completely masked the bitter taste of a bitter flavoured tablet. *Conclusion* The

study showed that MedCoat made tablets easier to swallow for people with difficulties swallowing tablets and that it masked the taste of bitter tasting tablets. MedCoat could therefore be a valuable tool to aid the oral taking of tablets for patients who have difficulties swallowing tablets.

Keywords Coating · Compliance · Oral medication · Swallowing · Tablets · Taste

Impact of findings on practice

- Patients having difficulties swallowing tablets with a rough surface or a bitter taste could be helped by using MedCoat.
- Health care professionals can enhance their quality of care by considering that MedCoat can solve a relatively common problem of swallowing tablets with a bad taste.
- Non compliance due to difficulties in swallowing tablets could be reduced by the use of MedCoat.

Introduction

Many patients experience difficulties when taking medicine in the form of tablets and capsules. In a large survey performed by general practitioners in Norway, 26% of the adult patients stated that they had difficulties swallowing tablets [1]. The study found that the taste, size, surface and form of the tablet were significant explanatory variables for these difficulties.

These difficulties not only cause inconvenience for a large proportion of the population, they can also have a

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negative impact on patient compliance in taking the medication [2]. Surveys show that only 20–50% of prescribed medicine is taken as directed, which in turn decreases the effect of the medication and increase healthcare costs [3, 4].

Recently, a novel disposable device called MedCoat has been developed by Med Coat AB in Sweden, which enables the user himself to apply a thin coating to most types of tablets just before oral administration. The purpose of the coating is to make tablets easier to swallow by making the surface of the tablet slippery, increasing the saliva flow and masking the taste of the tablet. The coating also contains flavouring to improve the taste of tablets. All ingredients in the coating are food approved and each coating weights approximately 0.2 g. The coating contains maltitol syrup, vegetable fat, gelatine, citric acid, sugar ester, curcumin and flavouring. A literature search and evaluation have been performed at the Division of Clinical Pharmacology at the Karolinska Institute in Sweden to explore if ingredients in the MedCoat coating may interact with drugs thereby effecting their therapeutic effects. The outcome of this evaluation was that such interactions are very unlikely to occur [F. Sjöqvist, unpublished data]. Disintegration tests have been performed at the Department of Pharmacy at the Uppsala University in Sweden to evaluate the effect of the MedCoat coating on the disintegration of some types of tablets and capsules [G. Alderborn and C. Olsson, unpublished data]. In these tests the MedCoat coating prolonged the disintegration time of tablets with on average 47 s.

Aim of the study

The aim of the study was to explore the swallow-enhancing and taste-masking properties of MedCoat for people who experience difficulties swallowing oral tablets.

Method

The study was performed between October 2006 and November 2006 as a single centre study at the Department of Otolaryngology, Kaunas Medical University Hospital (KMUH), Lithuania. Only placebo tablets were used in the study and no subjects were assigned to participate in any health-related interventions to evaluate the effects on health outcomes.

In total 41 subjects (20 male and 21 female) were enrolled in the study. The volunteer subjects were recruited by putting an advertisement at the Department of Otolaryngology, KMUH, Kaunas, Lithuania. The average age

Table 1 The age distribution of the subjects in the study

| Age distribution | Male <i>n</i> = 20 | Female <i>n</i> = 21 | Total <i>n</i> = 41 |
|------------------|--------------------|----------------------|---------------------|
| 18–24 years | 11 | 9 | 20 |
| 25–44 years | 6 | 8 | 14 |
| 45–64 years | 3 | 4 | 7 |

was 30 years, and ages ranged from 18 to 64 years. All 41 subjects completed the study (Table 1).

Each subject was to test all variables. The main inclusion criteria were as follows: subjects should be healthy volunteers and should (as judged by the subject) at least sometimes have difficulties swallowing tablets (e.g. depending on the type of tablet taken).

Exclusion criteria included subjects who (as judged by the subject) could not swallow tablets. Subjects with dysphagia or dysgeusia (as judged by the subject) were also excluded from the study.

Study design

First the subjects had to answer general questions concerning their intake of tablets.

Then the subjects were asked to swallow six tablets arranged into three pairs. The first pair of tablets swallowed comprised a non-flavoured placebo tablet and an identical tablet coated with MedCoat. The second pair was a half non-flavoured placebo tablet and an identical half tablet coated with MedCoat. The third pair was a bitter flavoured placebo tablet (flavoured with Bitter Flavour 050619A from Firminich SA, Switzerland) and an identical tablet coated with MedCoat. The tablets in each pair were swallowed separately and in a randomized order. The tablets used were uncoated oblong placebo tablets (whole and divided) of the same size and shape (19 × 10 × 6 mm). Each tablet was swallowed with a minimum of 20 ml of water. After both tablets in each pair had been swallowed, the subject was asked if one of the tablets was easier to swallow than the other. If so, the subject was asked if that tablet was “a little bit easier”, “easier” or “much easier” to swallow.

Finally, the subjects were asked to put a bitter flavoured tablet coated with MedCoat in their mouth and suck on it for 5 s and then take it out. The procedure was then repeated with an identical but uncoated bitter flavoured tablet. The subjects were informed that both tablets had the same bitter flavour but that the first tablet was coated. Subjects were then asked if the coating on the first tablet camouflaged the bitter taste “completely”, “most of it” “not so much” or “not at all”.

Research personnel applied the MedCoat coating to all the tablets just before the test commenced.

Table 2 Subjects' comparative opinions on which tablet was the easiest to swallow

| Type of placebo tablet | Coated much easier | Coated easier | Coated a little bit easier | No difference | Uncoated a little bit easier | Uncoated easier | Uncoated much easier |
|------------------------|--------------------|---------------|----------------------------|---------------|------------------------------|-----------------|----------------------|
| Non-flavoured | 22 (53.7%) | 10 (24.4%) | 8 (19.5%) | 1 (2.4%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Non-flavoured, half | 22 (53.7%) | 7 (17.1%) | 11 (26.8%) | 1 (2.4%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Bitter flavoured | 25 (61.0%) | 8 (19.5%) | 8 (19.5%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |

The tablets swallowed in each test were one uncoated placebo tablet and one identical placebo tablet coated with MedCoat

Statistical methods

With a sample size of 40 subjects, it was calculated that an exact binomial test with a two-sided significance level of 0.05 would have 90% power to detect the difference between the null hypothesis proportion of equal preference in ease of swallowing, $p_c = p_u = 0.50$ and the alternative proportion, $p_c = 0.75$. With an estimated fraction of at most 10% of the subjects being not evaluable, e.g. not being able to swallow any tablet, it was assumed that at most 45 subjects would have to be included in the study.

Exact calculations of two-sided 95% confidence intervals for proportions were based on the binomial distribution. Tests of the null hypotheses that the probability to prefer coated tablets (p_c) is equal to the probability to prefer uncoated tablets (p_u) were tested applying exact, 2-sided tests of the binomial probability $p_c = p_u = 0.5$. P values of <0.05 were considered statistically significant.

Results

Most of the subjects (25 or 61.0%) said that they took on average 7–14 tablets a week.

Of the 41 subjects, 40 (97.6%) found it less difficult to swallow the whole and half non-flavoured placebo tablets coated with MedCoat compared to identical uncoated tablets (95% confidence interval 87.1–99.9%). Twenty-two subjects (53.7%) stated that it was “much easier” to swallow the whole and half non-flavoured placebo tablets that were coated with MedCoat.

All 41 subjects (100.0%) found it less difficult to swallow bitter flavoured placebo tablets coated with MedCoat compared to identical uncoated tablets (95% confidence interval 91.4–100.0%). Twenty-five subjects (61.0%) stated that it was “much easier” to swallow the bitter flavoured placebo tablets that were coated with MedCoat (Table 2).

For the three types of tablets tested, the differences in favour of the coated tablets were statistically significant ($P < 0.001$ for each comparison). No differences in gender or age regarding the subjects' opinions on the ease of swallowing could be observed.

In the third part of the study, 41 (100.0%) of the subjects stated that MedCoat completely masked the bitter taste of a bitter flavoured tablet (95% confidence interval 91.4–100.0%).

Discussion

For the tablets tested, the differences in swallow ability in favour of the tablets coated with MedCoat were statistically significant ($P < 0.001$ for each comparison).

Study limitations

This study was performed on adults aged 18–64 years. However, difficulties swallowing tablets are also common among other age groups. In the Norwegian study referred to above over 70% of the children below 10 years of age had difficulties swallowing tablets [1]. Research also shows that unpleasant taste is one of the greatest challenges in paediatric medicine when it comes to drug treatment compliance [5]. A large proportion of the elderly population also has difficulties swallowing tablets due to, e.g. dysphagia [6, 7].

Study recommendations

To be able to generalize the results in this study to be valid for other types of tablets and age groups more types of tablets need to be tested and other age groups have to be studied.

Conclusion

The study has shown that MedCoat made tablets easier to swallow for people with difficulties swallowing tablets and that it masked the taste of bitter tasting tablets. MedCoat could therefore be a valuable tool to aid the taking of oral tablets for patients who have difficulties swallowing tablets, thereby increasing patient compliance.

Acknowledgements The authors would like to acknowledge Martin Ålenius, M.Sc. for statistical assistance.

Funding This study was supported by Med Coat AB, Stockholm, Sweden. Med Coat AB supplied the MedCoat coating but had no role in the study design; nor in the collection, analysis, and interpretation of data; nor in the preparation, review, or approval of the manuscript; nor in the decision to submit the manuscript for publication.

Conflicts of interest The authors have no conflicts of interest other than the source of funding.

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