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RESEARCH ARTICLE

Long-term results of oxybutynin treatment for palmar hyperhidrosis

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Abstract
Purpose Palmar hyperhidrosis (PH) is a common illness that significantly impacts Quality of Life (QOL). Oxybutynin offers excellent short-term results, but long-term follow-up results are limited. We evaluated its effectiveness in a large group of patients who did not have surgery and who had at least 6 months of follow-up.
Methods Between September 2007 and September 2013, 570 consecutive patients were enrolled in our institutional protocol regarding the "pharmacological-first" treatment of primary PH with oxybutynin. Fifty-nine were lost to follow-up, and the data were available for 511 patients treated for at least 6 weeks. Data recorded at the start of the protocol, 6 weeks after beginning treatment, and during patients' final visits were analyzed.
Results 112 patients (21.9 %) did not improve and were referred for surgery (sympathectomy). Eight (1.56 %) developed significant side effects (e.g., dry mouth) and discontinued therapy. Thirty (5.9 %) preferred surgery over pharmacological treatment. 111 have not yet received treatment for 6 months. The 246 patients with more than 6 months of follow-up (median 16 months, range 6–72) were analyzed, as follows: 90.2 % experienced moderate or great improvement in their PH; 90.34 % experienced improvement at other sites of hyperhidrosis following a median of 16 months.
Conclusion Among patients with good initial responses to oxybutynin, more than 90 % experienced moderate or great improvement in their palmar sweating, as well as in their hyperhidrosis in other sites, after 6 months. The

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results were particularly favorable in those patients with BMI <25 kg/m^2, and in those who noted an improved QOL after 6 weeks.

Keywords Hyperhidrosis · Hand · Oxybutynin · Cholinergic antagonists

Abbreviations

BMI	Body mass index
CH	Compensatory hyperhidrosis
PH	Palmar hyperhidrosis
QOL	Quality of life
VATS	Video assisted thoracic sympathectomy

Introduction

Excessive sweating in the palms of the hands—*palmar hyperhidrosis* (PH)—affects patients' quality of life (QOL) and compromises their professional, social, emotional, and leisure activities [1]. It usually begins during childhood and is the most common presentation of hyperhidrosis [2–5].

Non-operative treatments (topical agents, botulinum toxin and iontophoresis) have demonstrated limited efficacy [1, 6]. Surgery—video-assisted sympathectomy (VATS)—is the treatment of choice due to its low risk and high success rate. However, it is associated with compensatory hyperhidrosis (CH), usually a troublesome complaint, with up to 94 % of patients reporting some degree of this discomfort [2–4, 7, 8].

Patients with primary hyperhidrosis exhibit higher expression levels of acetylcholine and alpha-7 nicotinic receptors in their sympathetic ganglia [9].

Oxybutynin is an anti-muscarinic drug that was first associated with the resolution of hyperhidrosis in 1988 [10]. Recently, oxybutynin has been described [11, 12] as an excellent initial alternative form of treatment for hyperhidrosis; it has been used for the treatment of plantar [13], axillary [14], and facial hyperhidrosis [15] and was evaluated in a randomized, placebo-controlled trial [5]. Short-term results regarding pharmacological treatment for PH have been published [16–18], but long-term results regarding treatment with this particular drug are lacking.

The aim of this study was to assess the long-term efficacy of oxybutynin in a large series of consecutive patients ($n = 246$) treated with low doses of oxybutynin for at least 6 months (median = 16 months).

Patients

This was a non-randomized, uncontrolled study conducted in accordance with the appropriate institutional ethical boards (Protocol 01582112.6.1001.0071). Data were retrieved using our dedicated and prospective institutional protocol, which is standardized and has been used since 2001 for all patients with hyperhidrosis.

Between September 2007 and September 2013, 570 consecutive patients with a primary complaint of PH were enrolled in our "pharmacological-first" protocol.

Figure 1 graphically represents the series, treatments and outcomes over time, as follows: 570 patients were enrolled; fifty-nine failed to attend their first follow-up visit. Of the initial 511 subjects, 246 patients were followed for more than 6 months, as their follow-up periods ranged from 6 to 72 months (median = 16 months), and represent the population under study, as follows: 168 females and 78 males. Ages ranged from 4 to 61 years (average 22 years). This subgroup was comparable with the general population of 570 patients in terms of age, gender, body mass index (BMI), distribution of excessive sweating, and complaints.

Patient demographics are included in Table 1.

PH was rarely their only complaint, as most patients (96.75 %) demonstrated hyperhidrosis at other sites of the body, as follows: plantar in 238 (96.75 %), axillary in 117 (47.56 %), facial in 36 (14.64 %), and thoracic and abdominal hyperhidrosis in 29 (11.79 %).

Patients weighting >40 kg adhered to the following protocol: during the first week, patients received 2.5 mg of oxybutynin once a day at bedtime. Between days 8 and 21, they received 2.5 mg twice a day; beginning on day 22, they received 5 mg twice a day. Pediatric patients weighing less than 40 kg received the same treatment for the first 3 weeks, but their doses were not increased following day 21.

Three evaluations were undertaken for the purpose of this study. The first occurred before medication; the second

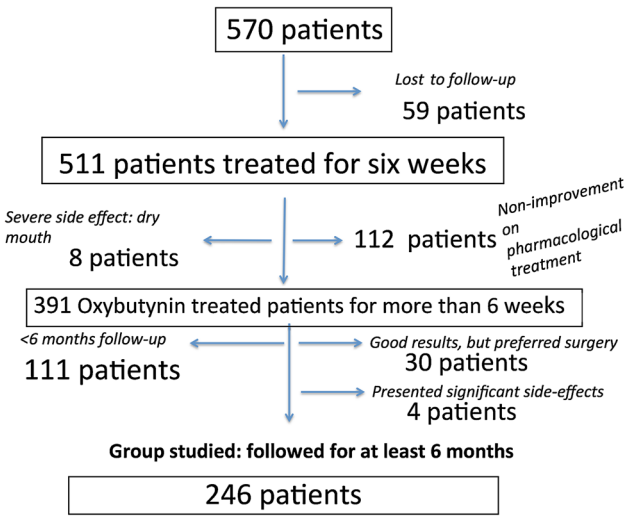

Fig. 1 Follow-up algorithm of pharmacologically treated patients with palmar hyperhidrosis

Table 1 Demographics and quality of life before and after treatment

		%
Male	$n = 78$	31.7
Female	$n = 168$	68.3
Age (range)	4–61	
Age (average ± standard deviation)	22 ± 9	
Age (median)	20	
Body mass index (BMI): average ± standard deviation	22.5 ± 4.0	
BMI (median)	22.1	
BMI (range)	14.2–36.6	
Pre-treatment quality of life		
Very poor	$n = 188$	76.42
Poor	$n = 54$	21.95
Good	$n = 3$	1.21
Very good	$n = 0$	0
Excellent	$n = 1$	0.42
Total	$n = 246$	100
QOL after 6 weeks of treatment		
Much worse	$n = 0$	0
Slightly worse	$n = 0$	0
The same	$n = 8$	3.25
Slightly better	$n = 108$	43.91
Much better	$n = 24$	52.84
Total	$n = 246$	100

BMI body mass index in kg/m^2, *QOL* quality of life

following 6 weeks of treatment, and the final evaluation occurred at least 24 weeks following the start of oxybutynin therapy. The following items were evaluated: (1) patients' initial QOL using a validated questionnaire for patients with hyperhidrosis [19]; patients who were not sexually active received a maximum score of 85, as 15 points were related to sexual activity. We corrected their score to a maximum of 100 using a rule of three, so that all scores were comparable. (2) patients' clinical improvement after 6 weeks; (3) patients' QOL after 6 weeks of treatment; (4) patients' clinical improvement at the final visit (the final consultation, which occurred at least 6 months after the beginning of treatment); (5) patients' complaints of pharmacological side effects after 6 weeks, and at the final visit; (6) patients' impressions of the amelioration of their hyperhidrosis symptoms at other sites, at the last visit.

Hyperhidrosis' negative impact on QOL before treatment was classified into five different levels, which were calculated as summed total scores from the protocol. The higher the level, the greater the impact, and the poorer the QOL. When the total was >83, QOL was considered very poor; from 68 to 83, poor; from 52 to 67, good; from 36 to 51, very good; and from 20 to 35, excellent.

Improvements in QOL after treatment were also classified into five different levels. When greater than 83, QOL was considered much worse; from 68 to 83, slightly worse; from 52 to 67, the same; from 36 to 51, slightly better; and from 20 to 35, much better.

Patients completed the clinical improvement questionnaire according to their subjective perceptions of the improvements in their sudoresis. They evaluated their conditions on a scale of 0 (no improvement) to 10 (absence of hyperhidrosis). Improvements were classified as null when the score was 0; slight, 1 to 4; moderate, 5 to 7; or great, 8 to 10.

The following items were studied: negative impact of hyperhidrosis on QOL before treatment, improvement in QOL following treatment, evolution of PH (comparing results after 6 weeks and at the last follow-up visit), improvement at other sites of hyperhidrosis at the last visit, and complications.

To assess predictors in patients' self-perceived amelioration of palmar sweating at the last visit, we divided patients into the following two groups: the first included patients who awarded grades of 0–4 (null/slight amelioration) to their symptoms at the last consultation, regarding the amelioration of their PH, and the second included the remaining patients (with moderate/great improvement), whose grades ranged between 5 and 10 at their final visit.

For the above-mentioned analysis, data relating to the following characteristics were studied: gender, BMI, pre-treatment QOL, and QOL after 6 weeks of treatment.

Statistical analysis

Means and standard deviations (SDs) were used in the descriptive analysis of parametrically distributed continuous variables, whereas frequencies were used for categorical variables. McNemar's test was used to compare self-reported improvements in hyperhidrosis and dry mouth over time at two consecutive analysis time points, and the kappa coefficient was used for analysis. Fisher's exact test and Pearson's Chi Square Test were used to compare groups.

The significance level for all tests was $P = 0.05$.

Results

Patients' QOL before and after treatment is presented in Table 1; more than 98 % of patients reported poor or very poor QOL, and only 3 % did not experience any improvements in QOL following 6 weeks of treatment.

Improvements in sweating after 6 weeks and at the last visit are presented in Table 2. After 6 weeks, 97.2 % of

Table 2 Comparisons of self-assessments of improvement in hyperhidrosis after 6 weeks of treatment and at the last visit

Improvement after 6 weeks		Improvement at last visit			
		Null/slight	Moderate	Great	Total
Null/slight	Count	5	1	1	7
	% of Total	2.0	0.4	0.4	2.8
Moderate	Count	11	52	38	101
	% of Total	4.5	21.1	15.4	41.1
Great	Count	8	30	100	138
	% of Total	3.3	12.2	40.7	56.1
Total	Count	24	83	139	246
	% of Total	9.8	33.7	56.5	100.0

McNemar's test $p = 0.002$. Kappa 0.332. Consistency 63.8 %. Worsening 20 %. Enhancement 16.2 %

patients reported moderate or great improvements in sweating. At the last visit, 90.2 % of patients reported moderate or great improvements in sweating.

Comparing the categories of improvement at the 6 weeks' analysis and at the last evaluation (Table 2) 63.8 % of patients remained in the same category of improvement, whereas 20 % were "downgraded," and 16.2 % improved over the course of the study. The changes in the sub-categories were statistically significant (McNemar's test $p = 0.002$).

Improvements at other sites of hyperhidrosis at the last evaluation included the following: 54.21 % of patients demonstrated great improvement, 36.13 %, moderate, and 9.66 % demonstrated null or slight improvement in their plantar hyperhidrosis ($n = 238$). Regarding axillary sweating, ($n = 117$), 56.41 % of patients demonstrated great improvement, 35.9 %, moderate, and 7.69 % demonstrated null or slight improvement. Regarding facial sweating, ($n = 36$), 66.67 % of patients demonstrated great improvement, 30.56 %, moderate, and 2.74 % demonstrated null or slight improvement. Regarding thoracoabdominal hyperhidrosis ($n = 29$), 48.27 % of patients demonstrated great improvement, 48.27 %, moderate, and 3.45 % demonstrated null or slight improvement.

Comparisons of dry mouth after 6 weeks and at the last visit are included in Table 3: 63 % of patients remained in the same category (absent/light or moderate/severe) throughout the study period, whereas 22.4 % improved, and 14.6 % reported worsening symptoms.

No major side effects (e.g., constipation, intestinal obstruction) occurred in this population. Minor and less frequent side effects included slight headache in 21 subjects (8.1 %), somnolence/drowsiness in 18 (7.3 %), and urine retention in 7 (2.8 %), none of which were reasons for patients to discontinue treatment.

Table 3 Complaints of dry-mouth after 6 weeks of treatment and at the last visit

Six weeks		Last visit		Total	McNemar *p*
		Absent/light	Moderate/severe		
Absent/light	*n*	88	36	124	0.059
	%	35.8	14.6	50.4	
Moderate/severe	*n*	55	67	122	
	%	22.4	27.2	49.6	
Total	*n*	143	103	246	
	%	58.1	41.9	100.0	

McNemar's test $p = 0.059$. Kappa 0.259. Consistency 63 %. Worsening 14.6 %. Enhancement 22.4 %

Table 4 Comparison between the group that experienced null or slight improvement in sweating at the last visit with the group that experienced moderate or great improvement

	Null/slight improvement		Moderate/great improvement		*p*
	n	%	*n*	%	
Gender					
Female	16	9.5	152	90.5	0.857#
Male	8	10.3	70	89.7	
Body mass index					
Below 25 kg/m^2	14	7.2	180	92.8	**0.010#**
Above 25 kg/m^2	10	19.2	42	80.8	
Age					
<14 years-old	5	10.0	45	90.0	>0.99*
15–40 years old	18	9.7	167	90.3	
Over 40 years old	1	9.1	10	90.9	
Pre-treatment QOL					
Very poor	21	11.2	167	88.8	0.540*
Poor	3	5.6	51	94.4	
Good	0	0.0	3	100.0	
Very good	0	0.0	0	0.0	
Excellent	0	0.0	1	100.0	
QOL after 6 weeks of treatment					
Much worse	0	0.0	0	0.0	**0.019***
Worse	0	0.0	0	0.0	
The same	2	25.0	6	75.0	
Better	15	13.9	93	86.1	
Much better	7	5.4	123	94.6	

* Fisher's exact test

\# Pearson's chi square test

An analysis of the results regarding age, gender, BMI, pre-treatment QOL and QOL after 6 weeks of treatment is presented in Table 4. Patients with BMIs lower than 25 kg/m^2 ($p = 0.01$), as well as patients with an improved quality

of life after 6 weeks, ($p = 0.019$) tended to have more favorable outcomes following long-term treatment than their counterparts.

Discussion

Oxybutynin offers excellent short-term results in the amelioration of hyperhidrosis. The primary contra-indication is closed-angle glaucoma. Apart from that, it is a safe medication but has limited tolerability as a result of antimuscarinic side effects, particularly at doses over 15 mg/day [20]. Doses of 10mg/day, when increased in a manner similar to the doses used in our protocol, have been shown to be effective, while lowering the incidence of side effects, and improving treatment adherence.

An earlier series [17] demonstrated that more than 80 % of patients experienced improvements in self-perceived sweating following 6 weeks of treatment, and more than 70 % experienced improvements in QOL.

These initial findings encouraged us to study the long-term consequences of oxybutynin use. Therefore, a large cohort ($n = 570$ patients) that began pharmacological treatment with oxybutynin was analyzed; their progress was monitored, and we focused those patients who exhibited favorable initial responses (6 weeks) and were treated for at least 6 months. We attempted to determine if improvements were maintained over longer periods of time and if tachyphylaxis occurred. Unfortunately, due to the retrospective nature of our study, we could not determine if sweat gland size was reduced following long-term treatment with oxybutynin. Prospective studies regarding this matter may be useful.

Concerning overall patient characteristics, most of our patients were females, as is customary in the setting of hyperhidrosis [1, 2, 21–23], and young (median 20 years), which is also typical for PH. Most females who seek medical attention for hyperhidrosis do so in the second or third decades of life [3, 24].

Of the 570 subjects studied, 59 (10.35 %) failed to return for their 6th week medical appointment. We believe that most of the patients lost to follow-up may have been anxious and were unwilling to continue taking a medication that did not provide favorable short-term results and that many of these patients experienced severe side effects (e.g., dry mouth, somnolence). A previous study [17] noted that 29.49 % of patients were lost to follow-up (41 patients were lost from a cohort of 139). We believe that our knowledge of good initial outcomes and our emphatic clarifications for patients regarding the expected risks and benefits of pharmacological treatment resulted in a smaller number of patients being lost to follow-up.

The current study endpoint was to evaluate the effectiveness and side effects profile of oxybutynin in patients treated for at least 6 months; as patients dropped out of the study within the first 6 weeks, it is our impression that the degree of attrition bias regarding our endpoint (efficacy of oxybutynin and occurrence of side effects after at least 6 months) was not substantial. The external validity (or generalization) of our findings is most likely genuine. In other words, patients who responded well and adhered to treatment for more than 6 months experienced favorable results, whereas those who did not deal well with oxybutynin's side effects (or did not improve after taking medication) appeared to have undertaken an excise in futility, but stopped before 6 months.

Self-reporting (on a scale from 0 to 10) of patients' impressions of their overall improvement was used, as opposed to an objective assessment of hyperhidrosis (which is technically feasible [25] with sudorometers, but at only a specific point in time, rather than throughout the day). Hyperhidrosis is a bothersome—but not lethal—condition, and the goal of treatment was the subjective amelioration of the patient's symptoms; therefore, self-reporting was deemed an adequate method of data collection. The retrospective nature of this study made it impossible to collect objective data from this population.

In spite of the positive results noted regarding excessive sweating, some patients did not tolerate oxybutynin's side effects; eight of 511 (1.56 %) experienced encouraging results but stopped the medication at 6 weeks because of excessive dry mouth. Following 6 weeks of treatment, four other participants (1.02 %) discontinued oxybutynin due to side effects (three: excessive dry mouth; one: clinical signs of vasculitis, which could not be directly linked to the medication but lead to discontinuation of the drug).

After 6 weeks, seven patients (2.8 %) reported null or slight ameliorations in PH but continued treatment. We believe this continuation occurred because sudoresis was ameliorated considerably in other parts of the body (which would not be routine after sympathectomy) and resulted in patients developing a preference for pharmacological treatment (over preference for surgery).

We found that improvements in sweating resulted in similar improvements in QOL, as approximately 3 % of patients did not note improvements in excessive sweating (Table 2), and the same proportion (Table 1) reported the same QOL following 6 weeks of treatment (i.e., no improvement in their QOL).

At the last visit (median = 16 months), 20 % of patients were found to have experienced a worsening of their improvement category (a patient who reported great improvement after 6 weeks and moderate improvement at the last visit was considered to have worsened, for example). One possible reason was non-adherence, which

included missed doses and "drug holidays." Due to the retrospective nature of this study, it was not possible to ascertain adherence via direct questioning or via other methods. Another possible reason was tachyphylaxis, an occurrence that has not yet been reported, to the best of our knowledge.

Nevertheless, 16.2 % of patients experienced improvements in their categories, and more than 90 % of patients reported moderate or great improvements in PH over the course of the study. This apparent contradiction may be explained by the idea that experiencing worsening symptoms does not necessarily lower a patient's overall satisfaction with medical care (i.e., there may be variations in perceived amelioration of sweating, but these are not significant enough to cause patients to cease medication use). We believe that because of these encouraging results, patients who initially respond well to medication may adhere to treatment indefinitely.

The sub-analysis suggests that patients with lower (<25 kg/m^2) BMIs tended to have better outcomes. This does not mean that excessive BMI should be a contraindication for oxybutynin, as overweight individuals experienced excellent responses, although their responses were not as favorable as those of their lighter counterparts. These findings are indeed favorable, as obesity is associated with increased intra-operative risks and a higher CH rate [26] in the setting of VATS, making this population particularly suitable for clinical management, although these individuals should also be encouraged to lose weight.

Likewise, the fact that patients with better QOL following 6 weeks of treatment tended to experience better outcomes by the final visit should not preclude patients who did not experience such significant initial responses from continuing treatment.

It is our group's opinion that when a patient considers surgical treatment for hyperhidrosis, it is of the utmost importance that he or she receives education that clarifies the risks of the peri-operative period (which are uncommon [27]), as well as the risk of CH. Regrets following the procedure are not rare, unfortunately [28], and pre-operative education and a "pharmacological-first" approach decreases the risk of treatment dissatisfaction for both patients and physicians.

If the initial results are sub-optimal (e.g., significant side effects or no improvement after 6 weeks of therapy), VATS or topical therapy should be considered, as these circumstances may represent pharmacological treatment failure. However, if patients have responded well after 6 weeks, they tend to benefit from therapy, as they maintain moderate or great improvements in their palmar HP, as well as at other sites of significant sweating, and the side effects are tolerable.

Conclusion

Our data demonstrate that anticholinergic treatment with oxybutynin is feasible and yields considerably positive results for patients able to maintain therapy for 6 months; following a median of 16 months, 90 % of patients displayed either moderate or great improvement in excessive sweating. The results were better in patients with BMIs lower than 25 kg/m^2 and in patients who reported experiencing better QOL after 6 weeks.

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Conflict of interest The authors declare no conflicts of interest.

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