PP02

Long-term safety and efficacy of Glycopyrronium tosylate in patients with primary axillary hyperhidrosis: a systematic review and meta-analysis

Eman A Nada¹, Abdallah A. Helal², Mallak E Kaddorah³, Mohamed M Hesn⁴, Suha Y Hasan⁵, Jeremiah O Daniel⁶ and Mohamed Abd-ElGawad²

Faculty of Pharmacy, Tanta University, Gharbia, Egypt; ²Faculty of Medicine, Fayoum University, Fayoum, Egypt; ³Faculty of Pharmacy, Yarmouk University, Irbid, Jordan; ⁴Damietta Faculty of Medicine, Al Azhar University, Cairo, Egypt; ⁵Faculty of Medicine, University of Benghazi, Benghazi, Libya; ⁶Faculty of Clinical Sciences, College of Health Sciences, Obafemi Awolowo University, Ile-Ife, Osun, Nigeria

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Presenter: Jeremiah Daniels (jeremiahdanielmd@gmail.com)

Background: Hyperhidrosis, a condition characterized by excessive sweating, affects $\approx 4.8\%$ of the US population. (1) Glycopyrronium tosylate (GT) is a topical anticholinergic drug approved for primary axillary hyperhidrosis (PAH) treatment. (2) However, no meta-analysis exists on GT's long-term safety and efficacy.

Aim: To evaluate the long-term safety and efficacy of GT as a treatment for PAH.

Methods: We systematically searched PubMed, Scopus, and ClinicalTrials. gov. Study selection, quality assessment, and data extraction followed the eligibility criteria. The primary endpoints were changes in the Dermatology Life Quality Index (DLQI), Hyperhidrosis Disease Severity Scale (HDSS), and Axillary Sweating Daily Diary (ASDD) or Axillary Sweating Daily Diary – Change (ASDD-C). Safety endpoints included mydriasis, dry mouth, urinary hesitation, and treatment-emergent adverse events (TEAEs). Statistical analysis was conducted using RevMan 5.1.

Results: Our meta-analysis demonstrated that topical GT is clinically effective in treating PAH. GT significantly improves the quality of

life of patients, as measured by the DLQI (MD = -2.81, 95% CI = [-4.04, -1.59], P = 0.001), HDSS (OR = 3.72, 95% CI = [2.92, 4.74], P = 0.001), and ASDD/ASDD-C (OR = 4.91, 95%CI = [3.75, 6.44], P = 0.001). Adverse effects such as mydriasis, dry mouth, and urinary hesitation were observed; however, no difference was found between GT and control groups in serious TEAEs, deaths, and severe TEAEs.

Conclusion: Topical GT is effective with minimal side effects, providing a valuable option for patients unresponsive to or experiencing significant side effects from other treatments.

Efficacy outcomes:

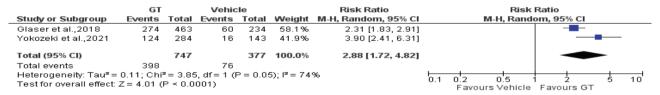
DLQI, change from BL to week 4.

	GT			Vehicle				Mean Difference	Mean Difference		
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI		
Pariser et al., 2018	8.3506	6.0016	405	4.6432	6.0443	206	49.4%	3.71 [2.70, 4.72]	_		
Yokozeki et al.,2021	5.6	5.4	329	3.6	4.9	165	50.6%	2.00 [1.05, 2.95]	-		
Total (95% CI)			734			371	100.0%	2.84 [1.17, 4.52]	-		
Heterogeneity: Tau² = Test for overall effect:	'		,	P = 0.02);	I= 83%	ı			-4 -2 0 2 4 Favours Vehicle Favours GT		

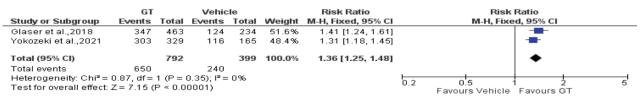
HDSS.

	GT Vel		Vehic	ehicle		Risk Ratio	Risk Ratio	
Study or Subgroup	Events Total		Events	s Total Weight		M-H, Fixed, 95% CI	M-H, Fixed, 95% CI	
Glaser et al.,2018	276	463	65	234	65.6%	2.15 [1.72, 2.67]	-	
Yokozeki et al.,2021	159	329	34	165	34.4%	2.35 [1.70, 3.23]	- 	
Total (95% CI)		792		399	100.0%	2.21 [1.85, 2.66]	•	
Total events	435		99					
Heterogeneity: Chi²=	0.20, df =	1 (P =	0.05 0.2 1 5 20					
Test for overall effect:	Z = 8.58 (P < 0.0	Favours Vehicle Favours GT					

ASDD/ASDD-C.



Sweat production response at week 4.



Safety outcomes:

Pruritus.



Blurring of vision.



Keywords: hyperhidrosis; axillary; efficacy; Glycopyrronium tosylate

References

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