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분말형 및 액상형 히알루로니다제의 알레르기 유발 가능성 비교 분석: 1,056명의 임상 사례를 통한 안전 투여 가이드라인 제시

(Comparative Analysis of Allergic Potential Between Powder-form and Liquid-form Hyaluronidase : A Clinical Study of 1,056 Patients and Implications for Safe Administration)

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Purpose: Hyaluronidase is essential for managing hyaluronic acid filler complications. This study evaluates the allergic potential of powder-form hyaluronidase (BM hyrunidase & H-lase) compared to liquid-form hyaluronidase (Hirax). Based on clinical data from three institutions, this research aims to provide a verified safety profiles and standardized screening protocols.

Methods: A retrospective analysis was conducted on clinical records and intradermal allergy skin test (AST) results from a total cohort of 1,056 patients. This study compared the powder-form group (n=958; BM hyaluronidase n=843, H-lase n=115) and the liquid-form group (n=98; Hirax). AST positivity rates were analyzed to evaluate formulation-dependent immunogenicity.

Results: The powder-form formulations demonstrated a significantly higher AST positivity rate (BM hyaluronidase 14.35%, H-lase 7.8%) compared to the liquid-form, which maintained a near-zero positivity rate in primary screening. However, cross-reactivity was observed where powder-positive patients occasionally reacted to conventional liquid forms.

Notably, recombinant human hyaluronidase (Tergase) showed high purity and minimal reactivity even in sensitized individuals. These disparities are attributed to protein denaturation and immunogenic stabilizers (e.g., lactose) inherent in the lyophilization of powder forms.

Conclusion: Liquid-form hyaluronidase provides a superior safety profile with a significantly lower immunogenic potential than powder-form alternatives. However, since hypersensitivity reactions remain a significant clinical risk even with improved formulations, relying solely on formulation choice is insufficient. Therefore, establishing a routine AST protocol is essential for early detection of hypersensitivity. Furthermore, implementing a standardized prophylaxis strategy, including pre-medication for high-risk cases, is a critical clinical mandate to prevent severe complications such as airway edema and ensure patient safety.

Variable		BM Hyrunidase (N=843)	H-lase (N=115)	Hirax (N=98)
Gender, n (%)	Female	783 (92.9%)	53 (46.1%)	43 (43.9%)
	Male	59 (7.0%)	62 (53.9%)	55 (56.1%)
Age (years)	Mean ± SD	34.4 ± 8.0	50.3 ± 18.5	45.4 ± 21.4
AST results, n (%)	Positive	121 (14.35%)	9 (7.8%)	0 (0.0%)
	Negative	722 (85.65%)	106 (92.2%)	98 (100.0%)

Table 1. Baseline characteristics and allergy skin test (AST) results across hyaluronidase formulations. Powder-form groups show higher AST positivity rates compared to the liquid-form group, which demonstrates no positive reactions.

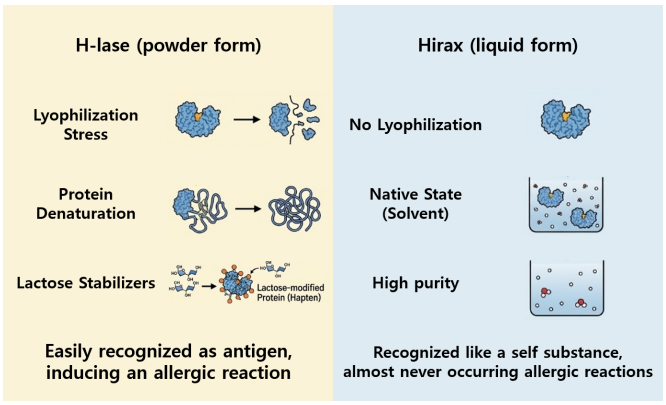

Fig 1. & 2. Baseline characteristics and allergy skin test (AST) results across hyaluronidase formulations. Powder-form groups show higher AST positivity rates compared to the liquid-form group, which demonstrates no positive reactions.