Brief Report

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Sensory testing assessment of dosage forms designed to resist overdose

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SUMMARY: Overdose incidence has increased among young individuals, particularly involving psychotropic and over-the-counter (OTC) drugs. However, there is limited information regarding how the physical form of medications—such as tablet size or thickness—affects the ability to take large doses. This study aims to determine which tablet characteristics (size, thickness, and volume) can discourage overdose by using sensory testing methods. The diameters and thicknesses of tablets commonly used in overdosing were measured. Additionally, dummy tablets were three-dimensionally (3D) printed, after which sensory tests were conducted to evaluate how many tablets could be comfortably consumed in large quantities, as well as the ease of consumption, rated on a 5-point scale. The respondents were students (average age: 21.3 ± 2.1 years, n = 253). Results indicate that OTC drugs typically have larger and thicker tablets compared with prescription drugs. Sensory tests of 3D-printed dummy tablets found that smaller tablets are easier to ingest in large numbers, whereas larger and thicker tablets are harder to consume in bulk. For tablets with the same diameter, a 5-mm thickness tends to make overdose more difficult compared with a 2-mm thickness. Importantly, tablets with a combined diameter and thickness of 13 mm or more and a volume of at least 190 mm^3 are less likely to be overdosed. These findings can assist pharmacists in selecting appropriate dosage forms for patients at risk of overdose and provide pharmaceutical companies with guidance during product development.

Keywords: Overdose, sensory test, tablets, 3D printer, pharmacist

1. Introduction

The incidence of overdose among young individuals has increased, particularly involving psychotropic and over-the-counter (OTC) medications (*1–3*). Patients who have experienced an overdose often repeat the behavior for self-harm or suicide attempts (*4*). Notably, even when the initial intent is self-harm, the hazard ratio for subsequent suicidal behavior compared with controls is approximately 42 (*5*). Tablets are commonly used in self-harm overdoses and are frequently administered orally (*6*). Careful selection of dosage forms is critical, particularly for patients prone to recurrent overdoses (*4*). Consideration should be given to tablet sizes that are less likely to cause overdose.

Pharmacists and registered drug sellers are responsible for preventing overdoses by acting as gatekeepers (*7*). These professionals must also recognize signs of suicidal ideation, actively listen, and monitor individuals (*8,9*) while using their expertise to select and modify dosage forms (diameter and thickness) based on available medications.

Research on tablet formulations has primarily focused on improving patient adherence by assessing preferred formulations. For example, studies indicate that participants favor model formulations in which the sum of the major/minor axes and thickness does not exceed 22 mm, with thickness ranging from 2 to 6 mm (*10,11*). Additional investigations into swallowing difficulties have examined the effects of head position relative to tablet size (*12*) and the impact of coatings (*13*). However, in scenarios where individuals intentionally ingest large quantities of tablets, perceptions of tablet size and dimensions may differ from those observed in everyday contexts; data addressing this aspect are currently insufficient. The ideal tablet size should balance deterring overdose and ensuring ease of swallowing for typical patients.

Psychotropic drugs are most frequently implicated in overdoses (*1*). Similarly, for OTC drugs such as caffeine, diphenhydramine, and cold medicines, information regarding ingredient characteristics and types is readily available (*14-16*). Furthermore, oral tablets constitute the predominant dosage form associated with overdoses. However, empirical evidence regarding dosage forms, specifically tablet size or thickness that are less

conducive to large-dose ingestion, is limited.

To address this gap, the present study utilizes sensory testing to identify appropriate tablet dosage forms (including diameter, thickness, and volume) that may reduce the likelihood of consuming large amounts of medication.

2. Materials and Methods

2.1. Measurement of OTC and prescription drug tablet diameter and thickness

This study examined 19 types of OTC drugs commonly implicated in overdoses, as identified by the FY2022 Ministry of Health, Labor, and Welfare Administrative Promotion Research Project Subsidy (Pharmaceutical and Medical Device Regulatory Science Policy Research Project) Participating Research Report in Japan (*17*). Tablet diameter and thickness for OTC drugs were measured using a digital caliper (Model: BDC100, measurement precision: ± 0.03 mm, AS ONE, Osaka, Japan), with mean values calculated from four replicates (n = 4). For prescription drugs, analysis focused on Classes 1, 2, and 3 psychotropic drugs designated under the Narcotics and Psychotropic Substances Control Law in Japan. The dimensions of 232 original and generic circular tablet formulations were assessed using Pharmaceutical Interview Forms, which are standardized documents provided by pharmaceutical companies in Japan.

2.2. Fabrication of dummy tablets *via* three-dimensional (3D) printing

Dummy tablets were modeled using 3D Builder software (Microsoft Corporation, Redmond, WA, USA). Cylindrical models were constructed, setting diameter (major and minor axes on the X- and Y-axes, respectively) and thickness (Z-axis). Tablet edges were chamfered to conform to standard tablet geometry (Figure 1), and all dummy tablets were produced in white. In total, 10 types of dummy tablets were created,

Figure 1. Diagram of dummy tablets produced using a 3D printer. (A) Top view of dummy tablets. (B) Side view of dummy tablets; d: diameter (mm), t: thickness (mm). (C) Tablets and packs were used in the test. A sensory test was conducted in which the tablets were available for visual and tactile examination.

comprising five diameters (3, 5, 8, 11, and 15 mm) and two thicknesses (2 and 5 mm) per diameter. The designs were realized using a stereolithography 3D printer (Elegoo Mars 2, Elegoo LCD., Shenzhen, China) following the manufacturer's instructions, with Water Washable resin SK02W (Felidentia Capital Ltd., Tokyo, Japan).

2.3. Participants and sensory testing with dummy tablets

The recruitment period spanned from June 28th, 2024, to February 6th, 2025. A total of 253 university and graduate students participated in the survey, primarily individuals in their twenties—an age demographic that aligns with most drug overdose patients. Participants were recruited after the study was explained and informed consent was obtained.

Ten dummy tablets, fabricated *via* 3D printing, were individually placed in transparent bags labeled A–J for the sensory test, during which participants were permitted to observe and handle the tablets (Figure 1C, Table 1). The diameter and thickness of the dummy tablets were randomly assigned, and testing was conducted under the surveyor's supervision. Survey responses were collected electronically *via* a web-based questionnaire accessed *via* a QR code (Table 1). Participants received only alphabetic and visual information about the dummy tablets; numerical dimensions, including tablet diameter and thickness, were withheld (Figure 1C).

The sensory test included two main questions. Question 1 (Q1) asked participants: "If you are taking a large number of tablets, please choose the number of tablets that you can take.," with options ranging from 0 to 19, 20 to 39, 40 to 69, 70 to 99, and over 100 tablets (Table 1). Question 2 (Q2) assessed perceived ease of ingestion, stating: "If you are taking a large number of tablets, please rate the ease of swallowing on a 5-point scale (1-5: Difficult - Easy)" (Table 1).

2.4. Statistical analysis

All statistical analyses were performed using JMP Student Edition 19 (SAS Institute Inc., Cary, NC, USA), with a significance threshold set at $p < 0.05$. Cutoff values were determined employing the Youden Index method. According to Japan's Ministry of Internal Affairs and Communications, as of April 2025, approximately 23.37 million individuals were in their teens and twenties. Based on this population size, the required sample size for the survey was calculated to be 245 participants, assuming a 5% margin of error, an 80% collection rate, and a 95% confidence interval (CI). This sample-size calculation was described as a descriptive precision estimate rather than as an a priori sample-size determination.

2.5. Ethics approval

Table 1. Sensory test results about Overdose

dummy tablets (d, t)	I (3, 2)	F (3, 5)	C (5, 2)	B (5, 5)	A (8, 2)	D (8, 5)	E (11, 2)	H (11, 5)	G (15, 2)	J (15, 5)
Q1 *n* (%)										
0–19 Tablets	8 (3.2)	10 (4.0)	8 (3.2)	33 (13.0)	86 (34.0)	126 (49.8)	131 (51.8)	182 (71.9)	190 (75.1)	223 (88.1)
20–39 Tablets	12 (4.7)	28 (11.1)	45 (17.8)	79 (31.2)	101 (40.0)	79 (31.2)	85 (33.6)	49 (19.4)	42 (16.6)	19 (7.5)
40–69 Tablets	31 (12.3)	59 (23.3)	67 (26.5)	84 (33.2)	35 (13.8)	30 (11.9)	22 (8.7)	14 (5.5)	11 (4.3)	5 (2.0)
70–99 Tablets	33 (13.0)	54 (21.3)	57 (22.5)	32 (12.6)	11 (4.3)	12 (4.7)	9 (3.6)	4 (1.6)	3 (1.2)	2 (0.8)
more than 100 tablets	169 (66.8)	102 (40.3)	76 (30.0)	25 (9.9)	20 (7.9)	6 (2.4)	6 (2.4)	4 (1.6)	7 (2.8)	4 (1.6)
Q2 *n* (%)										
1 (difficult to take)	3 (1.2)	4 (1.6)	0 (0)	5 (2.0)	8 (3.2)	40 (15.8)	66 (26.1)	141 (55.7)	168 (66.4)	233 (92.1)
2	4 (1.6)	6 (2.4)	5 (2.0)	13 (5.1)	49 (19.4)	111 (43.9)	122 (48.2)	88 (34.8)	61 (24.1)	11 (4.3)
3	12 (4.7)	13 (5.1)	15 (5.9)	42 (16.6)	70 (27.7)	76 (30.0)	46 (18.2)	17 (6.7)	17 (6.7)	3 (1.2)
4	14 (5.5)	48 (19.0)	50 (19.8)	114 (45.1)	91 (36.0)	21 (8.3)	14 (5.5)	4 (1.6)	3 (1.2)	2 (0.8)
5 (easy to take)	220 (87.0)	182 (71.9)	183 (72.3)	79 (31.2)	35 (13.8)	5 (2.0)	5 (2.0)	3 (1.2)	4 (1.6)	4 (1.6)

Sensory test: About the dummy tablets (you can look and touch). Question 1 (Q1): If you are taking a large number of tablets, please choose the number of tablets that you can take. Question 2 (Q2): If you are taking a large number of tablets, please rate the ease of swallowing on a 5-point scale (1-5: Difficult - Easy). n = 253. The alphabetical order is the order of the exams. Smallest to largest order of dummy tablets. d: diameter (mm), t: thickness (mm).

This study was approved by the Ethics Committee of the Graduate School of Pharmaceutical Sciences, Chiba University (R049-1). Participants received both verbal and written explanations before scanning the QR code. Participation was voluntary and did not affect grades. Consent was obtained as participants indicated their agreement by selecting the consent box on the web-based questionnaire and submitting their responses. All participants were adults in Japan. All methods were carried out in accordance with the Declaration of Helsinki.

3. Results and Discussion

3.1. Investigation of the diameter and thickness of prescription and OTC drugs

To examine the diameter (d) and thickness (t) of round prescription drug tablets, data were obtained from the Pharmaceutical Interview Form, and correlations were analyzed (Figure 2A). The correlation between prescription drug diameter and thickness was weak ($\rho = 0.26$, 95% CI: 0.20-0.43, $p < 0.05$). The diameter distribution for these tablets predominantly fell within $6 < d \leq 8$ mm, with no examples observed below 4 mm or above 12 mm (Figure 2C). The thickness of round prescription tablets was primarily distributed between 2 and 3 mm, with no measurements below 1 mm or exceeding 5 mm (Figure 2E).

For OTC drugs used for overdoses, the diameter and thickness of round tablets were measured using a digital caliper, and averages were calculated ($n = 4$; Figure 2). Analysis demonstrated a strong correlation between diameter and thickness in round OTC tablets ($\rho = 0.61$, 95% CI: 0.45-0.90, $p < 0.05$; Figure 2B). Most OTC tablet diameters were within the 8–10 mm range, with none smaller than 4 mm or larger than 12 mm (Figure 2D). The most frequent thickness category was > 5 mm

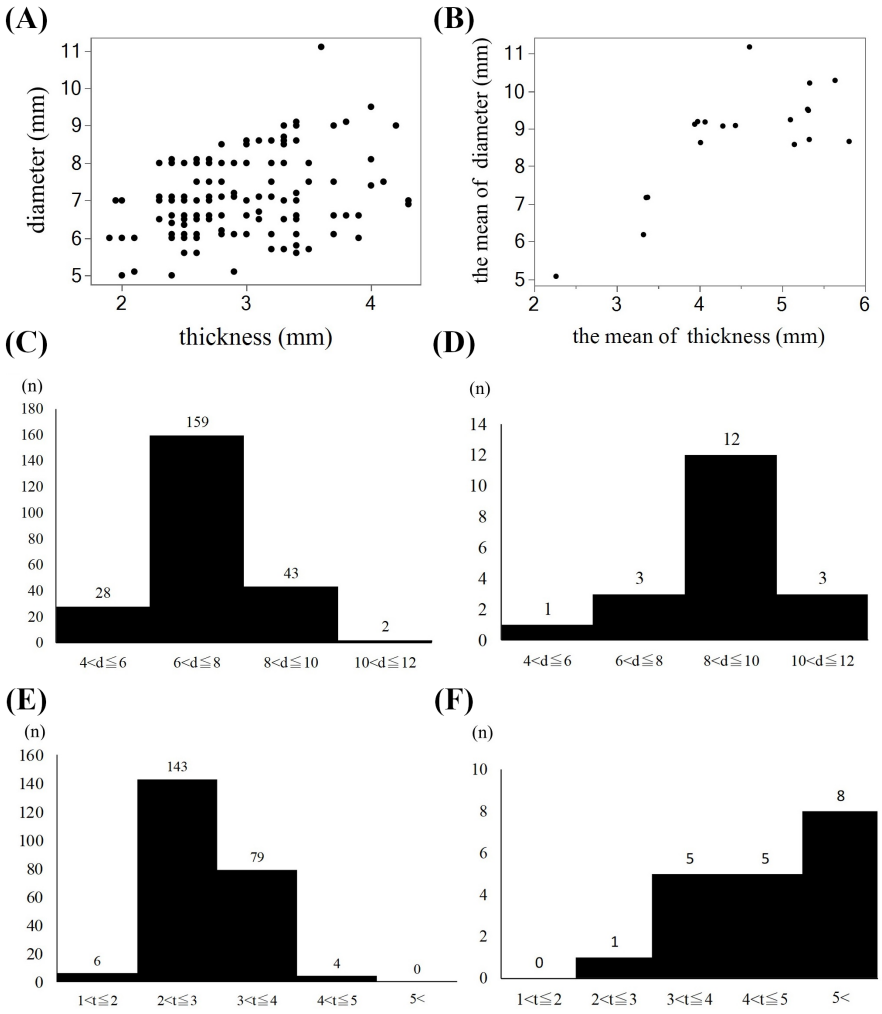

Figure 2. Diameter and thickness characteristics of prescription and over-the-counter (OTC) tablets. (A) Correlation between diameter and thickness of pharmaceutical products, $n = 232$, $\rho = 0.26$, 95% CI: 0.20–0.43, $p < 0.05$. (B) Correlation between mean diameter and mean thickness of OTC drugs, $n = 19$, $\rho = 0.61$, 95% CI: 0.45–0.90, $p < 0.05$. (C) Diameter distribution of prescription drugs. (D) Mean diameter distribution of OTC drugs. (E) Distribution of the thickness of prescription drugs. (F) Distribution of average thickness of OTC drugs; d: diameter (mm), t: thickness (mm). The vertical axis of C–F indicates *n*. Spearman's rank correlation coefficient was calculated.

(8/19); none had a thickness less than 2 mm (Figure 2F).

Regarding product trends, OTC drug tablets typically displayed a greater diameter and thickness than prescription drug tablets. Previous studies have reported a mean diameter of 7.6 ± 1.4 mm for 3,271 round prescription drug tablets (*18*). Similarly, the results of the current study indicated that most round OTC drug tablets had diameters within $8 < d \leq 10$ mm, with no tablets under 4 mm or over 12 mm. This trend underscores the observation that OTC drugs are generally larger in size and thickness than their prescription counterparts. Based on these findings, dummy tablets were produced for this study.

3.2. Response rate and participant characteristics

The required sample size for this survey was calculated to be 245, and 253 individuals responded, thereby fulfilling the adequacy criteria. With an estimated 300 surveys distributed, the response rate was 84.3% (253/300). The mean age of participants was 21.3 ± 2.1 years; male respondents (n = 111) had a mean age of 21.5 ± 2.6 years, while female respondents (n = 142) had a mean age of 21.1 ± 1.5 years.

3.3. Sensory test using dummy tablets

Dummy tablets were manufactured *via* 3D printing to facilitate sensory tests and to investigate appropriate dosage forms—such as diameter and thickness—to mitigate the risk of overdose (Figure 1C). Five different diameters were produced based on actual tablet sizes from prior investigations; extreme reference sizes of 3 mm and 15 mm, not present in surveyed products, were included. Tablets were prepared at thicknesses of 2 mm and 5 mm, resulting in ten variations subjected to sensory testing (Table 1).

Initially, participants were presented with Q1 (Table 1) to consider the maximum number of tablets they could consume when taking a large dose. For the small, 3 mm-diameter dummy tablets—which do not reflect any current medication—the highest proportion of respondents reported being able to take "more than 100 tablets," with 169 respondents (66.8%) for the 2 mm-thick tablets and 102 (40.3%) for the 5 mm-thick tablets. Conversely, among the 15 mm diameter dummy tablets, representing the largest size not found in actual medications, the percentage of respondents reporting the perceived ability to ingest more than 100 tablets was lowest: 7 respondents (2.8%) for the 2 mm thick tablets and 4 respondents (1.6%) for the 5 mm thick tablets. Among the tablets with a 5 mm diameter—the smallest available size—76 respondents (30.0%) were able to ingest more than 100 tablets at a thickness of 2 mm, while 25 respondents (9.9%) could do so at a thickness of 5 mm. For tablets with an 11 mm diameter—the largest available size—6 respondents (2.4%) were able to ingest more than 100 tablets at a thickness of 2 mm, while 4 respondents (1.6%) could do so at a thickness of 5 mm. These findings suggest that increasing tablet thickness (from 2 mm to 5 mm) reduces the ease of consuming large quantities, even when the diameter remains constant.

Subsequently, Q2 was asked to assess the perceived ease of bulk ingestion (Table 1). For the 3 mm-diameter dummy tablets, which are not representative of existing medications, the proportion of respondents who answered "easy to take" was highest: 220 (87.0%) for the 2 mm-thick tablet and 182 (71.9%) for the 5 mm-thick tablet. In contrast, for the larger dummy tablets (15 mm diameter), which were not present in the actual drug sample, only 4 respondents (1.6%) across both thicknesses answered: "easy to take." Regarding the 5 mm diameter tablets—the smallest available as medicine—183 respondents (72.3%) for 2 mm thickness and 79 (31.2%) for 5 mm thickness were rated as "easy to take." For tablets with an 11 mm diameter—the largest available as medicine—only 5 respondents (2.0%) for 2 mm thickness and 3 (1.2%) for 5 mm thickness reported they were "easy to take."

3.4. Tablet form (diameter and thickness) associated with reduced overdose risk

Based on the data obtained from the sensory tests, an evaluation was conducted to determine which tablet diameter and thickness were most likely to impede overdose (Table 1). The dummy tablets for which the highest proportion of respondents selected the lowest response category ("0–19 tablets") for "Q1. If you are taking a large number of tablets, please choose the number of tablets that you can take." had a diameter of 8 mm and a thickness of 5 mm (Tablet D; 126 respondents, 49.8%). Similarly, Tablets E, H, G, and J, which possess larger diameters and thicknesses than Tablet D, also received "0–19 tablets" as the most frequent answer to this question. Notably, for Tablet H (diameter: 11 mm; thickness: 5 mm), 71.9% of respondents selected the minimum category (0–19 tablets) when asked Q1. Additionally, tablets with a 15-mm diameter may further complicate the administration of large doses (Table 1).

3.5. Threshold for "diameter + thickness" and "volume" of tablets that are difficult to overdose

First, a generalized linear mixed model was constructed to control for within-participant correlation due to repeated measures. Receiver operating characteristic (ROC) analysis was employed to identify cutoff values for both "diameter + thickness" and "volume" to determine tablet formulations that are difficult to overdose (Table 1, Figure 3). Specifically, the threshold for "diameter + thickness" was verified using the ease-of-taking scores obtained from the sensory test, with a threshold set at ≤ 2 on a 5-point scale. The ROC analysis

revealed a cutoff value of 13, with an area under the curve (AUC) of 0.93, a 95% CI of 0.91–0.93, sensitivity of 0.91, and specificity of 0.84 ($p<0.05$).

Similarly, the cutoff value for tablet "volume" was determined using the same sensory test metric (≤ 2 on a 5-point scale). ROC analysis revealed a cutoff of 190 mm^3, with an AUC of 0.92 (95% CI: 0.91–0.93), sensitivity of 0.91, and specificity of 0.84 ($p<0.05$). The volume was calculated by treating each tablet as a cylinder.

Overdose of dextromethorphan (*19*) or diphenhydramine (*16*) can have profound effects. In Japan, MEDICON® (dextromethorphan) and RESTAMIN® (diphenhydramine) tablets are comparatively small, measuring 5–6 mm in diameter and 2–3 mm in thickness, and are available both by prescription and OTC. Dextromethorphan exhibits varying pharmacological effects based on the overdose amount; at high doses, it acts as an NMDA (N-methyl-D-aspartate) receptor antagonist, inducing hallucinations and dissociative symptoms *(20,21)*. Co-administration with CYP2D6 inhibitors, such as quinidine, sertraline, and diphenhydramine, can increase circulating dextromethorphan concentrations. There are also documented fatalities resulting from high-dose dextromethorphan ingestion alone (*19*). Diphenhydramine overdose can also produce severe cardiac effects, including cardiac arrest (*22*), for which no effective antidote exists. In the current study, these medications corresponded to Tablet C in the dummy tablet set. Notably, 76 participants (30.0%) selected "more than 100 tablets" as potentially ingestible at one time, while 183 (72.3%) rated the ease of taking large quantities at the maximum score of 5.

Regarding product size for future safety considerations, Tablet D (diameter: 8 mm; thickness: 5 mm) demonstrated the highest proportion of respondents (126, 49.8%) selecting the lowest value of "0–19 tablets" as the answer of Q1. This finding aligns with the ROC curve cutoff value for "diameter + thickness" of 13. Thus, Tablets D, E, H, G, and J—with larger dimensions—appear to impede excessive ingestion.

Accordingly, it is essential to optimize tablet size and thickness for medications with high overdose risk, balancing these modifications against normal patient use requirements. For safe drug formulations, prioritizing ease of administration may warrant maintaining a smaller tablet size, whereas larger tablets may be preferable for compounds with high toxicity in overdose situations. Furthermore, the results demonstrate that increasing thickness (5 mm *vs.* 2 mm) further reduces the likelihood of ingesting large doses, even when the diameter remains constant—a factor warranting consideration in pharmaceutical design.

This study has certain limitations. The findings rely on sensory testing with dummy tablets, as testing large quantities of actual tablets was not feasible. Consequently, verification was only conducted through sensory testing. Additionally, the participant group comprised solely young individuals due to the high rate of overdose reports in this demographic; thus, the findings may not apply to older adults. Moreover, although different tablet shapes can influence the results, this study considered only one shape. Hence, future investigations should examine the impact of various tablet shapes on overdose, including studies that compare pharmacokinetics across different tablet shapes. Larger tablets may increase swallowing difficulty, esophageal

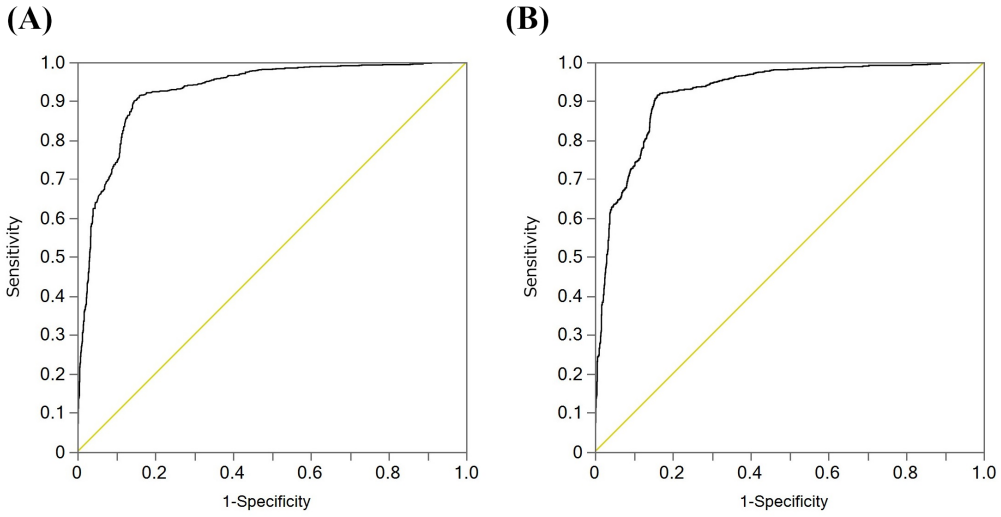

Figure 3. ROC curves for determining cutoff values of "diameter + thickness" and "volume" parameters for tablets that are difficult to ingest in large quantities. First, a generalized linear mixed model was constructed to control for within-participant correlation due to repeated measures. (A) ROC curve identifying the cutoff value of "diameter + thickness" for tablets with ingestion difficulty in large quantities. ROC analysis revealed a cutoff of 13 (AUC: 0.93, 95% CI: 0.91–0.93, sensitivity: 0.91, specificity: 0.84, $p < 0.05$). (B) ROC curve for determining the "volume" cutoff value in assessing tablet ingestion difficulty in large quantities. ROC analysis revealed a cutoff of 190 (AUC: 0.92, 95% CI: 0.91–0.93, sensitivity: 0.91, specificity: 0.84, $p < 0.05$).

sticking, choking, and poor medication adherence during normal use. It should also address adherence during daily treatment, risks to older adults, children, and patients with dysphagia, and the possibility that an individual may still complete an overdose by swallowing the tablets one at a time. Other overdose-prevention measures, including limiting package quantities, dispensing smaller supplies at shorter intervals, supervised medication administration, and restrictions on sales, should be discussed and compared with the tablet-size strategy. The size of the tablet should only be considered as one possible solution. This study included only a convenience sample of undergraduate and graduate students, without reporting their mental health status, history of self-harm or drug overdose, swallowing difficulties, or routine medication experience. Visual and tactile judgments made by healthy students cannot be considered a substitute for the actual behavior of patients at high risk of overdose. These precautions are necessary when generalizing research findings.

The findings of this study suggest that pharmacists can select and dispense formulations containing the same active ingredient, but designed to reduce the risk of overdose, for patients identified as a risk for overdosing, considering their dosage size. Furthermore, pharmaceutical manufacturers can now consider tablet sizes that minimize the potential for overdose on drugs commonly involved in such incidents or possessing high overdose risks, while maintaining ease of swallowing for most patients. These observations may inform the development of effective strategies for overdose prevention.

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