METHOD

The present study investigated the swallowing characteristics using qualitative and quantitative measures in adults above 18 years of age. This study was conducted in the department of Audiology and Speech Language Pathology at Kasturba Medical College, Mangalore. The study protocol was approved by the Institutional ethics committee at Kasturba Medical College, Mangalore.

Subjects: Human volunteers were recruited for the study based on the sample size formula \( n = \frac{Z^2_{1-\alpha/2} \sigma^2}{d^2} \), where \( \sigma \) is the Standard deviation, \( d \) is the precision and \( 1-\sigma/2 \) is the desired confidence level). A total of 800 individuals without complaints of swallowing participated in the study. They were divided into four groups depending on their age based on the classification suggested by Cichero, and Murdoch in 2003. The details are as follows.

<table>
<thead>
<tr>
<th>Groups</th>
<th>Age range</th>
<th>No of individuals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Males</td>
</tr>
<tr>
<td>Group I</td>
<td>18-40 years (Mean age=31 years)</td>
<td>N=100</td>
</tr>
<tr>
<td>Group II</td>
<td>41-59 years (Mean age=50 years)</td>
<td>N=100</td>
</tr>
<tr>
<td>Group III</td>
<td>60-75 years (Mean age=68 years)</td>
<td>N=100</td>
</tr>
<tr>
<td>Group IV</td>
<td>76-87 years (Mean age=82 years)</td>
<td>N=100</td>
</tr>
</tbody>
</table>

Table 4: Details of individuals who participated in the study

The exclusion criteria considered were history/presence of speech, language, neurological and swallowing disorders. Informed consent was obtained from each individual prior to the conduction of the study.
Procedure:

The study followed the cross-sectional control group design. Experiments were conducted in two phases. Phase 1 comprised of developing a qualitative assessment protocol for swallowing and phase 2 involved developing a normative for the quantitative measures such as submental EMG, nasal airflow monitoring and cervical auscultation.

a) Qualitative measures: This phase included developing a protocol for the Swallowing assessment. The tasks were included based on the formal and informal swallowing assessment tools available in the literature. The available tests which formed the base for this protocol development included Oral motor/Feeding rating scale (Jelm, 1990), Dysarthria/Dysphagia clinical battery (Linden, Kuhlemeier, & Patterson, 1993), Program for the assessment and instruction of swallowing (Mulpeter & Rosenfield, 1993), Burke Dysphagia Screening Test (Depippo, Holas & Reding, 1994), Bedside evaluation of dysphagia (Hardy, 1995), Dworkin-Culatta Oral Mechanism Exam and Treatment System (Dworkin & Culatta, 1996), Quick assessment protocol (Tanner & Culbertson 1999), Oral speech mechanism screening examination (Louis & Ruscello, 2000), Manns Assessment of Swallowing Ability (Mann, 2002), and Swallowing ability and function evaluation (Ross-Swain, Kipping & Yee, 2003). Those tasks which were suitable for both the adults and geriatric population were compiled.
The developed protocol focused on three main areas such as assessment of structure, assessment of function and assessment involving trial feeds (Appendix A). In the assessment of structure, various articulators such as lips, tongue, palate, jaws, cheeks, and teeth were observed for deviations and the responses were documented and not scored. In the sensory assessment, touch/tactile sensation was primarily addressed through light touch and deep pressure for the same articulators. The responses are scored as either normal or deviant on a two point rating scale, with scoring of 0 for normal functional limits and 1 for impaired function. In the motor assessment of swallowing, lips, tongue, cheeks, jaw, soft palate, pharynx, and larynx were assessed for the range, strength and speed of motion. Assessment of swallowing with trial feeds included dry swallow, thick liquid swallow, thin liquid swallow and solids. Protocol adopted for the assessment of trial feeds in individuals with dysphagia is detailed in the figure 1 and 2.

The scoring for motor assessment and phases of swallowing is based on a three point rating scale, i.e., 0-within functional limits, 1- mild to moderate impairment, 2-severe impairment. This pattern of numerical representation of swallowing behavior is expected to minimize the variability among the professionals in administration and scoring. Administration and scoring guidelines are listed in Appendix B.

Three subject experts in the field of clinical dysphagia reviewed the developed protocol for the task appropriateness and organization of the items. It was also field tested on ten individuals in each age group for the further validation before administering on 800 individuals.
Figure 2: Trial feed assessment chart for neurogenic dysphagia
Figure 3: Trial feed assessment chart for mechanical dysphagia
b) Quantitative measures: All quantitative swallowing measurements were performed using the Kay Digital Swallowing Workstation and Swallowing Signals Laboratory (Model 7120, Kay PENTAX, Montwale, NJ). It is a computer-integrated system for the simultaneous measurement of surface electromyography (sEMG), nasal airflow monitoring and cervical auscultation.

(a) Surface EMG: Surface EMG was used to evaluate the muscular activity associated with swallowing preparation. Muscle activity was recorded at a sampling rate of 500 Hz. It was ensured that all the males were shaved properly and the region of electrode placement was cleansed with spirit. The surface electrodes used were silver coated discs placed 1 cm apart from each other and they were placed on the submental musculature. The region of electrode placement on submental musculature was determined by having the individual press the tongue to the hard palate, which is expected to tense geniohyoid, mylohyoid and Anterior Belly of the Digastric muscles. Subsequently, electrodes were placed on the tensed muscles.

Figure 4: Submental electrode placement for sEMG
(b) Nasal airflow monitoring: Nasal airflow monitoring was used to measure the duration of apnea during swallowing. Respiratory coordination for swallowing was measured using a nasal catheter placed at the entrance of each individual’s nares. A Nasal respiratory flow was captured using a standard, 1.8 meter nasal cannula coupled to the Swallowing Signal Lab. The calibrated nasal cannula was used for each individual to ensure accurate measures. Nasal airflow direction was displayed on a waveform with a green positive trace representing expiration and a red negative trace representing inspiration. The sampling rate for the respiratory tracing was set to 250 Hz.

Figure 5: Nasal cannula placement for respiratory swallow coordination

(c) Cervical auscultation: Cervical auscultation was used to characterize the sounds of swallowing associated with each preparation. It was carried out by placing a stethoscope microphone on the thyroid lamina coupled to the Workstation by using the Swallow Signals Lab hardware and software to create a display of the captured waveform. The sampling rate for the respiratory tracing was set to 4000 Hz. Coupled with the SEMG peak, an acoustic burst assists in the identification of a swallowing event.
The individuals were requested to swallow the bolus in one complete action. Recording of the swallow commenced upon the tongue to liquid contact and the recording ceased post swallow, after the laryngeal movement was visualized. The specific bolus consistency and volume used for quantitative assessment are detailed below.

**Dry swallow:** It is defined as a swallow involving no external food or liquid.

**Thin Liquid swallow:** It is defined as a swallow involving intake of water.

**Thick liquid swallow:** It is defined as a swallow involving the ingestion of 20 ml of water mixed with the commercially available thin rice flakes (4 grams).

The samples were also collected using different volume of bolus. The following order was followed for trial feeds:

- Dry swallow,
- 5 ml of thin liquid,
- 10 ml of thin liquid
- 5 ml of thick liquid
- 10 ml of thick liquid.

The order of presentation of bolus remained the same for all the individuals.
Analysis:

A. Each individual's performance across the age and the gender on the swallowing assessment protocol was scored.

B. Raw sEMG waveform was displayed as a graphic trace on a computer screen. Measures derived from the sEMG waveform included onset and offset of swallow to determine the time duration for which the activity was present, peak (maximum) amplitude and the mean amplitude for the submental muscle activity.

![sEMG waveform](image)

Figure 7: sEMG waveform

C. Respiratory information (inhalation/exhalation) displayed as a waveform for all the swallowing attempts. It was linked to the Electromyographic activity and the respiratory events were identified which included were (1) inspiration, defined as a red downward line tracing; (2) swallowing apnea, defined as a black horizontal line; and 3) expiration, defined as the green upward line tracing. In the present study, swallow apnea as well as the respiratory phase where the swallow apnea occurred were measured for each volume and consistency of the bolus. Vertical cursors were superimposed at the onset and offset of the swallowing apnea, and the duration of apnea was measured.
Figure 8: Nasal airflow waveform

D. Each swallowing signal was displayed as an amplitude by time waveform. Vertical cursors were superimposed at the onset and offset of each signal and the duration of swallow was measured from the point on the waveform where acoustic signal could first be traced beyond the baseline to the point at which the amplitude of the signal returned to baseline. Also, peak amplitude and mean amplitude of swallow sounds were determined.

Figure 9: Acoustic waveform for the swallow sounds

All these measurements were carried out for each bolus type and volume of food taken for the study.

E. Statistical Analysis:

a. Descriptive statistics: Descriptive statistics were employed to describe all the qualitative and quantitative parameters under consideration. The mean and standard deviation for each measure was obtained for age, gender, bolus type and volume.
b. Internal consistency measure was carried out through cronbachs alpha coefficient to determine the reliability of the items on the test. Intraclass correlation coefficient was performed to find out the intra and inter judge agreement within and between the judges respectively.

c. Concurrent validity for the developed swallowing assessment protocol was established for aspiration through the measurement of sensitivity, specificity, positive predictive value, negative predictive value and the efficiency. For this purpose, videofluroscopy assessment was done on individuals with dysphagia along with the developed swallowing assessment protocol.

d. **Analysis of Variance:** All statistical analysis were performed using SPSS 10.0 for windows. An alpha level of 0.05 was used for all statistical tests including the post hoc tests. For each subsection in qualitative measures, two way ANOVA was performed with age and gender as the between group variables. For each of the dependent variables in quantitative measures, $4 \times 2 \times 2 \times 2$ (Age x Gender x Bolus type x Volume) repeated measure two way ANOVA was performed, with age and the gender as the between group factors and bolus type, and volume as the within group variables. This was followed by the Bonferonis post hoc test for the comparison across the age group and various consistencies of food. Since dry swallow was performed only once, two way ANOVA was performed with age and gender as the between group variables and dry swallow parameters as dependent variable. 0.05 level of significance was considered for all the analysis.