

Objective Gain vs Subjective Benefit in Patients with Bone Anchored Hearing Aids

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ABSTRACT

One possible shortcoming of bone anchored hearing aids is that even though objective gain measured through audiometric and speech tests is observed, certain patients describe little or even a reduction in subjective benefit in hearing.

This study aims to measure and compare these two parameters in the hopes of further understanding the role of BAHA's to treat different kinds of hearing loss. For subjective benefit the APHAB questionnaire was used whereas free field audiograms and free field speech in noise tests were used to measure objective gain. Of the total 29 number of patients only 9 percent reported a significant increase in subjective benefit whereas 21 and 25 of the patients had a significant increase in objective gain.

BONE ANCHORED HEARING AIDS (BAHA)

Bone anchored hearing aid's (or BAHA) are a type of device that is surgically implanted and designed to help people with hearing loss in specific situations (Kirtane, Mankekar & Chitranshi, 2010; Nevoux et al., 2018). The conventional type of hearing aids are usually air conduction hearing aids, which means that they transmit sound waves by conduction through air (den Besten et al., 2018; Rasmussen, Olsen & Nielsen, 2011). BAHA's stimulate the cochlea by transmitting sound waves through bones situated in our skull, through the temporal bone and into the cochlea (van Wieringen, De Voecht, Bosman & Wouters, 2011). Bone conduction therefore bypasses the outer and

middle ear (Kiesewetter, Ikari, Brito & Bento, 2013). Once the cochlea is stimulated, the information is converted into nerve signals and transferred to the brain via the vestibulocochlear nerve, where it is perceived as sound (Rasmussen, Olsen & Nielsen, 2011; van Wieringen, De Voecht, Bosman & Wouters, 2011).

BAHA's are indicated in a variety of different scenarios. These include patients with chronic middle ear problems, such as active cholesteatoma, and chronic external ear problems, such as chronic otitis externa or a chronically discharging ear (Kirtane, Mankekar & Chitranshi, 2010; Wazen, Spitzer, Ghossaini, Kacker & Zschommler, 2001). Another indication for BAHA's is in patients who have hearing loss along with

congenital defects of the ear that do not allow for the use of an air conduction hearing (Rasmussen, Olsen & Nielsen, 2011). Lastly, patients with single sided deafness will also benefit from BAHA's as it will assist in sound localisation by replacing the affected ear (Kiesewetter, Ikari, Brito & Bento, 2013; Löhler, Gräbner, Wollenberg, Schlattmann & Schönweiler, 2017). Single sided deafness patients are defined as patients who have lost all or most hearing in one ear, in which a conventional hearing aid is not helpful, but have good hearing in the other (van Wieringen, De Voecht, Bosman & Wouters, 2011). BAHA's are approved for children over the age of 5 in most European Union countries. For children under the age of 5, a BAHA alternative is advisable, with this being an adjustable soft head band transmitting sound through the skin (Kirtane, Mankekar & Chitranshi, 2010; Rasmussen, Olsen & Nielsen, 2011; Miller, 2019; Kruyt et al., 2020).

BAHA's have two distinct parts: a titanium bone implant and an external sound processor (Kiesewetter, Ikari, Brito & Bento, 2013; den Besten et al., 2018). The external microphone and sound processor of the bone-anchored device picks up sounds and converts them into vibrations to the embedded implant (Rasmussen, Olsen & Nielsen, 2011). In turn, the implant vibrates the surrounding bone, transmits sound waves in the inner ear that stimulate the cochlear hair cells and result in the firing of the vestibulocochlear nerve (van Wieringen, De Voecht, Bosman & Wouters, 2011).

Most bone anchored hearing aid's use a titanium-based implant (which is anchored in the temporal bone just above the mastoid process) and a sound processor (Kiesewetter, Ikari, Brito & Bento, 2013; Kirtane,

Mankekar & Chitranshi, 2010). The external microphone and sound processor of the bone-anchored device picks up sounds and converts them into vibrations to the embedded implant. An abutment connects the sound processor with the implant in the bone (Rasmussen, Olsen & Nielsen, 2011). This creates direct bone conduction and bypasses skin (den Besten et al., 2018). In contrast, traditional bone conduction hearing aids connect indirectly to the bone through unbroken skin (transcutaneous) and function by exerting pressure against the temporal bone (Kirtane, Mankekar & Chitranshi, 2010; van Wieringen, De Voecht, Bosman & Wouters, 2011; Nevoux et al., 2018). Direct bone conduction, provided by BAHA's provides superior transmission of sound as the signal is not weakened when passing through the skin, muscle and fat overlying the temporal bone (Rasmussen, Olsen & Nielsen, 2011; Miller, 2019; Boleas-Aguirre, Plano, de Erenchun Lasa & Beroiz, 2012).

SURGICAL IMPLANTATION

There are multiple ways one can perform BAHA surgery. These vary by the amount of soft tissue removal. The general surgical steps common to all are the following (Balslev, 2013; Kiesewetter, Ikari, Brito & Bento, 2013; Löhler, Gräbner, Wollenberg, Schlattmann & Schönweiler, 2017).

The skin site is marked generally 0.5cm posterior to the external auditory on a line adjacent to the top of the helix extending 45 degrees posterosuperiorly after which the hair in area around incision is shaved (Hameed & Watson, 2010; van Wieringen, De Voecht, Bosman & Wouters, 2011). This is usually over one of the thickest areas of the temporal bone (Balslev, 2013). Most

BAHA's come with a template with equal dimensions for the external processor (Kruyt et al., 2020). Local anaesthetic is usually injected prior to making the incision. The steps beyond the above vary according to methods listed below (Hameed & Watson, 2010; Wazen, Spitzer, Ghossaini, Kacker & Zschommler, 2001).

DERMATOME METHOD

This method maximizes surgical field access by removal of a specific area of tissue but is compromised with most tissue removal. It is particularly indicated in obese patients (Balslev, 2013). One of the major disadvantages of this method is prolonged scar healing time and larger hair loss area (Ghossaini, Spitzer & Borik, 2010). All the soft tissue is cut down to periosteum out within the confines of an inferiorly pedicled split-thickness skin graft that is created with a dermatome. The soft tissue is then beveled at the skin edges so that the graft slopes from periosteum directly up to surround skin when replaced (Hameed & Watson, 2010).

LINEAR INCISION METHOD

In this method, a linear incision is made, followed by a 4 mm punch at the implant site to remove skin and subcutaneous tissue (Hameed & Watson, 2010). The incision line is then extended down to subcutaneous tissue but leave periosteum intact. Thin skin flaps anterior and posterior to the implant are then created using a blade (Balslev, 2013). The area of hair loss in this method is significantly smaller than in the dermatome method and is limited to around 1cm squared around abutment (Wazen, Spitzer, Ghossaini, Kacker & Zschommler, 2001). Its

major advantage is shorter healing time and lower proportion of skin infections post operatively (Ghossaini, Spitzer & Borik, 2010). This method however is dependant on surgical experience and may be associated with a higher rate of skin overgrowth (Balslev, 2013; Cox, Alexander & Gray, 2003).

MINIMAL INVASIVE METHOD

In this method, scalp thickness is gauged by means of a calibrated instrument followed by a 4mm punch at the designated BAHA site (Hameed & Watson, 2010). The incision is then extended in both directions to the punch site and the planes elevated down to periosteum (Kiesewetter, Ikari, Brito & Bento, 2013). This method has the fastest wound healing time and is ideal for skin scalp with small thickness (Löhler, Gräbner, Wollenberg, Schlattmann & Schönweiler, 2017). It does not involve any hair shaving and is therefore ideal for patients with thinning hair. It is a fairly new procedure and its true complications are still to be studied (Wazen, Spitzer, Ghossaini, Kacker & Zschommler, 2001).

The drilling of the fixture guide hole is done after performing a cruciate incision in periosteum at site and lifting periosteum off bone in the area that is drilled. Continuous check that dura is not exposed using instruments such as a lacrimal probe (Balslev, 2013).

The same process is repeated for the countersink. In both cases the area is irrigated during and after drilling to clear any bone chips (Hameed & Watson, 2010; Kiesewetter, Ikari, Brito & Bento, 2013; Boleas-Aguirre, Plano, de Erenchun Lasa & Beroiz, 2012).

Placement of the fixture or abutment depends if it is a one stage or two stage system. In a one stage system: the abutment and fixture come as one piece (Wazen, Spitzer, Ghossaini, Kacker & Zschommler, 2001). In a two-stage system, the fixture is placed in the skull alone, and then the abutment is screwed onto the fixture separately (Balslev, 2013). It is done in the same way as the one stage except only the fixture is placed at the first visit. The abutment is placed after 6 months of osseointegration (Hameed & Watson, 2010; Löhler, Gräbner, Wollenberg, Schlattmann & Schönweiler, 2017).

Methods and Materials

For this study, a decision was made to measure subjective benefit in hearing by means of a standardized questionnaire. Several options were considered before deciding on using the APHAB questionnaire (Johnson, Cox & Alexander, 2010).

The APHAB questionnaire was eventually chosen for this study. This is a self-assessment questionnaire in which patients score the level of problems they are having in various situations. The APHAB was originally created to be used as part of initial hearing aid fitting, and as a standardized test for quantifying disability associated with the hearing loss. (Johnson, Cox & Alexander, 2010; Paul & Cox, 1995).

The abbreviated profile of hearing aid benefit (APHAB) measures subjective hearing loss by means of 24 questions which can be subdivided into four different sections, each of which consists of 6 questions which measure a different parameter to quantify subjective hearing gain. These are ease of communication (EC), reverberation (RV), background noise (BN)

and aversiveness (AV) (Cox, 1997; Turan, Unsal & Kurtaran, 2019).

Each question of APHAB is worded as a statement, such as “I can follow a conversation in groups of more than four people”. The patient must choose an answer based on how frequently the statement occurs by choosing from seven different answers which are: A. Always (99%), B. Almost Always (87%) C. Generally (75%) D. Half-the-time (50%) E. Occasionally (25%) F. Seldom (12%) G. Never (1%) (Cox & Alexander, 1995; Johnson, Cox & Alexander, 2010).

Every option is associated with a percentage number of occurrences which helps the user interpret the wording (Cox, Alexander & Gray, 2003). Patients were asked to read the questions carefully before answering specifically because of the fact that answers have opposite meanings in different questions ‘for example “A. Always” means a lot of problems in some questions and sometimes it means few or no problems in others (Johnson, Cox & Alexander, 2010). The APHAB questionnaire is specifically designed this way to ensure that users read each question carefully as they may otherwise be tempted to read only the first question or two carefully and then proceed to give the same answer to the rest, which disturbs the validity of the questionnaire (Cox, 1997). Studies have shown that informing patients about this prior to completing the questionnaire increases the likelihood of representative results. (Cox, 1997; Cox & Alexander, 1995; Turan, Unsal & Kurtaran, 2019; Miller, 2019).

Quite often patients expressed difficulty responding to a particular question because they felt they never experienced that specific situation in their daily life (Paul & Cox,

1995). When this occurred, an attempt to describe similar situation which the patient was familiar with was made (Kruyt et al., 2020). To choose a suitable alternative example, the following variables were considered: background noise level, reverberation, presence of visual cues and distance between origin of sound and the patient (Johnson, Cox & Alexander, 2010).

It is important to note that patients occasionally exaggerate the benefit provided by hearing aids because they are grateful for the overall service provided and praise the hearing aid excessively (Paul & Cox, 1995). To avoid this situation all patients are informed to fill the questionnaire as honestly and truthfully as possible including the negative aspects of the aid (Johnson, Cox & Alexander, 2010).

Once the patient has filled in the questionnaire, the data is submitted to a dedicated software program for analysis (NOAH). This program generates scores for each subscale and provides several graphical representations for analysis.

If the EC, RV, and BN and AV scores are all equal to or larger than 5 points with the aid on as opposed to the aid off then one can be fairly certain that the better-scoring fitting is truly superior. If the difference between scores with the aid on and off is equal to or larger than 10 points for all three subscales, the likelihood of this occurring by chance is only about 4%. When considering individual subscales, one must record a difference of about 22 points or more between aided and unaided scores for EC, RV or BN in order to be certain that the difference in scores represents a significant statistical difference. With regards to the AV subscale, one has to record a difference in score of 31 between

aided and unaided scores (Cox, 1997; Turan, Unsal & Kurtaran, 2019).

All of the patients were of Maltese nationality. Malta is a bilingual country (speaking both Maltese and English); however, because a few of the patients had some difficulty understanding English, a version of the APHAB that was translated in Maltese was used. This translated version was sourced from a separate group of researchers, after consent to use this version was obtained. (Miggiani & Tabone, 2016)

Data Analysis

The first task performed in the analysis is assessing the response pattern to see if it appears valid. Because the wording varies from item to item in the questionnaire and because some questions are worded in reverse (“always” meaning a few problems), a specific pattern of responses should be seen (Turan, Unsal & Kurtaran, 2019). The response alternatives should be used at least once and the pattern of usage should not be systematic but rather random-looking (i.e. the item marked should not be the same for several questions). If this pattern of response is present, it is very likely that the data is invalid and should therefore be interpreted with caution.

The last part of the analysis is the collection of scores generated by software. Five scores are generated for both the aided and unaided sections of the questionnaire. These are the ease of communication (EC) score, reverberation (RV) score, background noise (BN) score and adaptation of voice (AV) score and finally the global (GBL) score (Stenfelt, Håkansson, Jönsson & Granström, 2000). The GBL score is calculated by obtaining a mean average of the 4 subset scores. The final step in the software analysis

is to obtain the global benefit score which is calculated by subtracting the unaided GBL score from the aided GBL score (Cox, 1997; Cox & Alexander, 1995).

The APHAB questionnaire does not include any questions pertaining to local complications / issues that may affect the duration of use of the hearing aid even though these may be the main reason for reduced overall use (Cox, Alexander & Gray, 2003).

Objective gain in these patients was measured by means of a free field audiogram and free field speech in noise tests. This type of measurements, that were chosen as standard audiograms in patients with BAHA's, is not possible at our centre, as headphones would not adequately cover the external component of the BAHA device (Miller, 2019).

The free field audiogram and questionnaire were completed in the same clinic visit to avoid any possible differences in objective gain or subjective measurement that may occur if they are measured on different days.

The British Society of Audiology (BSA) protocol was used to perform the free field audiograms and speech in noise tests. The protocol uses several international standards to set parameters for the test and how it is conducted. One standard (BS EN ISO 8253-2:2009) was used to define test stimuli and sound field characteristics for free field audiometry and speech in noise tests as well as gives step by step instructions on how to perform the tests. It is also used to describe calibration protocol and give guidance on how to undergo maintenance procedures for equipment. (Stevenson et al., 2017; Kwak et al., 2020). Another standard (BS EN ISO 389-7:2005+A1:2016) was used as a reference

for normative data (reference hearing thresholds or RETSPL's) for pure tones in a free field of sound. Finally, the audiometric software and hardware used in this study complied with the BS EN ISO 8253 – 2:2009 standard, which gives specifications for frequency modulated tones and narrow band noises (Stevenson et al., 2017).

The free field audiology room used in this study was one defined as a quasi-free sound field. In a quasi-free sound field, the walls, ceiling and floor have a minimal effect on the sound waves produced by the speaker in the room with regards to amplitude and distortion. This condition is the most likely to be achieved in practice in any standard audiology room and is acceptable for the purpose of clinical threshold measurements. In an ideal scenario, a complete free sound field should be used when performing free field audiometry. This means that the walls, ceiling and floor of the room exert no effect on the sound waves produced by the speaker in the room. These conditions are available in an anechoic room only and is almost never available in a clinical environment (Stevenson et al., 2017).

A standard free field layout (with defined distance specifications set in the British society of audiology -BSA guidelines) was used when conducting the free field audiogram measurements. The audiological reference point was set at roughly the midpoint of the head of a hypothetical listener and it was further defined as the midpoint of a straight line connecting the patient's ear canal openings when positioned in the listening position in the sound field (Stevenson et al., 2017)

The free field audiogram was performed whilst masking the better hearing ear. Standard masking protocol (as listed in BSA

free field guidelines), was used and masking sound intensity was titrated according to thresholds being tested in free field (Stenfelt, Håkansson, Jönsson & Granström, 2000; Stevenson et al., 2017). For a patient with single sided deafness masking was not performed, as this was assumed to have interfered with the detection of correct thresholds, seeing that bone conducted sound stimuli transmitted from the BAHA are still heard in the normal ear (Kruyt et al., 2020; Kwak et al., 2020). This presents an obvious limitation in measuring objective gain in free field audiometry; however, this was mitigated by turning the patient's head 45 degrees, having the BAHA ear facing the speaker through which sound was being produced directly. (Miller, 2019). This movement in head position was presumed to be enough to produce a head-shadow effect on the better hearing ear (quoted in literature to be more than 10dB in quasi-free sound field audiology rooms). This effect in theory allows for adequate measurement of the difference in thresholds in the deaf ear with the BAHA device on and off (Stenfelt, Håkansson, Jönsson & Granström, 2000; Kwak et al., 2020). The test was performed twice, once with the BAHA on and another time with the BAHA off.

Results

This study included a total of 29 patients. One patient had the BAHA changed a few years after her first surgery into a more modern unit in view of local complications. Ten point three percent (n=3) of the patients were paediatric patients and the remaining 89.7% (n=26) were adults. The age of the patient cohort ranged from 7 years to 58 years old. In total, 19 of the patients were female whereas only 10 were male.

The indications for use of BAHA were chronic external ear pathology in 3% (n=1) of the patients, chronic middle ear pathology in 10% of the patients (n=3), cochlear and retrocochlear pathology in 55% of the patients (n=19) and congenital defects of the external ear in 20% of the patients (n=6). Forty-four point eight percent (n=13) of the patients had a mixed type of hearing loss, 37.9 % (n=14) of the patients had a pure conductive loss, whereas 17.2% (n=5) had a pure sensorineural loss. Fifty-five percent of the patients (n=16%) were diagnosed as having single sided deafness.

The average number of hours of BAHA use per day was 6.5 hours with a range of use from 1 hour to 16 hours. The average number of years of BAHA use was 5 years with the specified time frame being from 2011 to 2019.

On an initial analysis, none of the questionnaires were deemed invalid when considering the repeated answer clustering phenomenon described in the methods section above. After completing the questionnaire, all patients described occasional difficulty in answering questions based on one or more of the specific scenarios in the questionnaire which they rarely or never experienced in daily life. Whenever this happened, another similar scenario was described verbally to the patient and the new answer was recorded based on this new scenario.

The mean average APHAB aided and unaided subset scores, aided and unaided global scores and global benefit scores are listed in Table 1. The APHAB scores according to subscale are represented in Figure 1.

(See Table 1)

(See Figure 1.)

After the measurement of the APHAB scores, patients were then classified into 2 distinct groups, these being patients without a statistically significant subjective benefit and those with a statistically significant subjective benefit. The former group included patients that had a global benefit score of 20 or less whereas the latter included patients with a global benefit score of more than 20.

A total of 9 patients reported a statistically significant increase in subjective benefit, whereas 20 patients did not report a statistically significant increase in such benefit ($p < 0.001$).

With regards to objective gain, a significant objective gain was defined as a difference between aided and unaided pure tone average scores of 10dB or more. Pure tone average was calculated by obtaining a mean average of thresholds at 500Hz, 1kHz, 2kHz and 4kHz. Twenty-four of the 29 patients had a significant objective gain recording during free field audio by the above criteria. The mean PTA scores for all patients were 40dB and 55dB for aided and unaided measurements respectively.

(See Figure 2.)

A total of 21 patients had a statistically significant increase in this type of measured objective gain whereas 8 patients did not have a statistically significant increase in such benefit ($p < 0.001$).

When one further subdivides the patients into two distinct groups, when comparing results between objective gain and subjective benefit, an interesting conclusion can be drawn. These two distinct groups are patients

with single sided deafness (and normal or near normal hearing in the better ear) vs all other patients. This subdivision is illustrated in all of the figures mentioned above.

Discussion

With the results mentioned above, we can draw several conclusions.

Firstly, this study reveals a statistically significant difference between subjective benefit and measured objective benefit. Secondly it appears that with regards to objective gain, patients with single sided deafness (and normal or near normal hearing) tend to benefit less overall than patients with other kinds of pathology. This is most probably due to the fact that, with single sided deafness, the placement of a BAHA does not help in restoring ability to localize sound in any way (even though the patient is listening to two different kinds transmitted sounds [air and bone], the hearing ear is unable to distinguish between the two). The BAHA therefore only helps by transmitting sounds to the better hearing ear that would otherwise be lost by the head shadow effect. This rarely accounts for a difference in thresholds of more than 15dB (Schröder, Ravn & Bonding, 2010).

The results in this study seem to indicate that there is a statistically significant difference in subjective benefit and objective gain in global BAHA users. However, there is no statistically significant difference in these two parameters for patients with pure single sided deafness. This latter point was also concluded in several studies (Baguley et al., 2009; Monini et al., 2015; Faber et al., 2015) To our knowledge, only one study has measured and compared subjective benefit and objective gain simultaneously and the results of this are conducive to our findings

(van Wieringen et al., 2011). However, several studies report an overall benefit in hearing in global BAHA users following insertion of a BAHA (Badran et al., 2006; McLarnon et al., 2004).

This study seems to indicate that some of the BAHA patients describe overall little to no benefit despite having significant objective gain in the measured tests. This discrepancy teaches us to consider all factors when making a clinical decision as to when a BAHA is indicated in the future. One must keep in mind all the shortcomings and inconveniences associated with BAHA use (such as reverberation, local complications, cosmetic outcome, technological inconveniences, ease of use, etc) when discussing BAHA as a treatment to certain kinds of hearing loss (den Besten et al., 2018).

Further studies comparing these two parameters simultaneously are needed to reliably confirm if there is indeed a difference in between subjective gain and objective benefit. Even though statistical significance was obtained with our number of patients, larger numbers are needed in future studies to reliably compare these two parameters.

This study has several limitations. Firstly, the number of patients studied is not very large, despite obtaining statistically significant results. A restudy of patients at our hospital should be considered with a larger number of patients. Secondly, this study includes patients who have different brands of BAHAs all of which have different components and have been proven to have non identical levels of gain. This confounding variable is one of the main limitations in the study. Lastly, it is important to note that measuring true

objective gain of a BAHA is limited because of the fact that masking can never be completely adequate, especially when using audiograms as a measurement.

Free field audiometry (or any other type of audiometry) is not a truly subjective measure of BAHA function. For this to be truly measured, one must make use of devices like a skull simulator or similar. A skull simulator is a device that measures bone anchored hearing aid response inside a hearing instrument test (HIT) box. Traditionally, HIT measurements are performed for air conduction hearing aids and do not provide adequate stimulation for BAHAs. They also lack the coupling mechanism that is needed to test for a bone anchored hearing aid response (Van Ess & Wazen, 2009).

The skull simulator is a type of device that houses an accelerometer which allows connection to a bone anchored hearing aid. This provides the correct coupling mechanism and vibratory stimulation that is required to test a bone anchored aid within a HIT box (Schnabl et al., 2014).

Measured outcomes are similar to those in air conduction hearing aid HIT measurements and include harmonic distortion, peak response, equivalent noise-input, frequency response and battery drain time.

This type of devices are not readily available at our ENT / Audiology clinic so a free field audiogram was chosen as a means to measure objective gain in this study.

Conclusion

This study demonstrated that there is indeed a statistical difference between measured objective benefit and subjective gain when considering all patients with BAHAs but no discrepancy when measuring in patients with

single sided deafness only. This finding seems to suggest two related but separate points. Firstly, post-operative objective measure should be interpreted with caution alone, and should ideally be used in conjunction with subjective measures, such as the use of a questionnaire. Secondly, the indications for BAHA insertion should be evaluated thoroughly prior to making the decision to proceed, especially if patients do not classify under the classification of single sided deafness.

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APPENDIX

Table 1

Aided					Unaided					Global benefit score
GBL	EC	RV	BN	AV	GBL	EC	RV	BN	AV	
23	9	26	26	36	27	9	28	34	50	4

Figure 1.

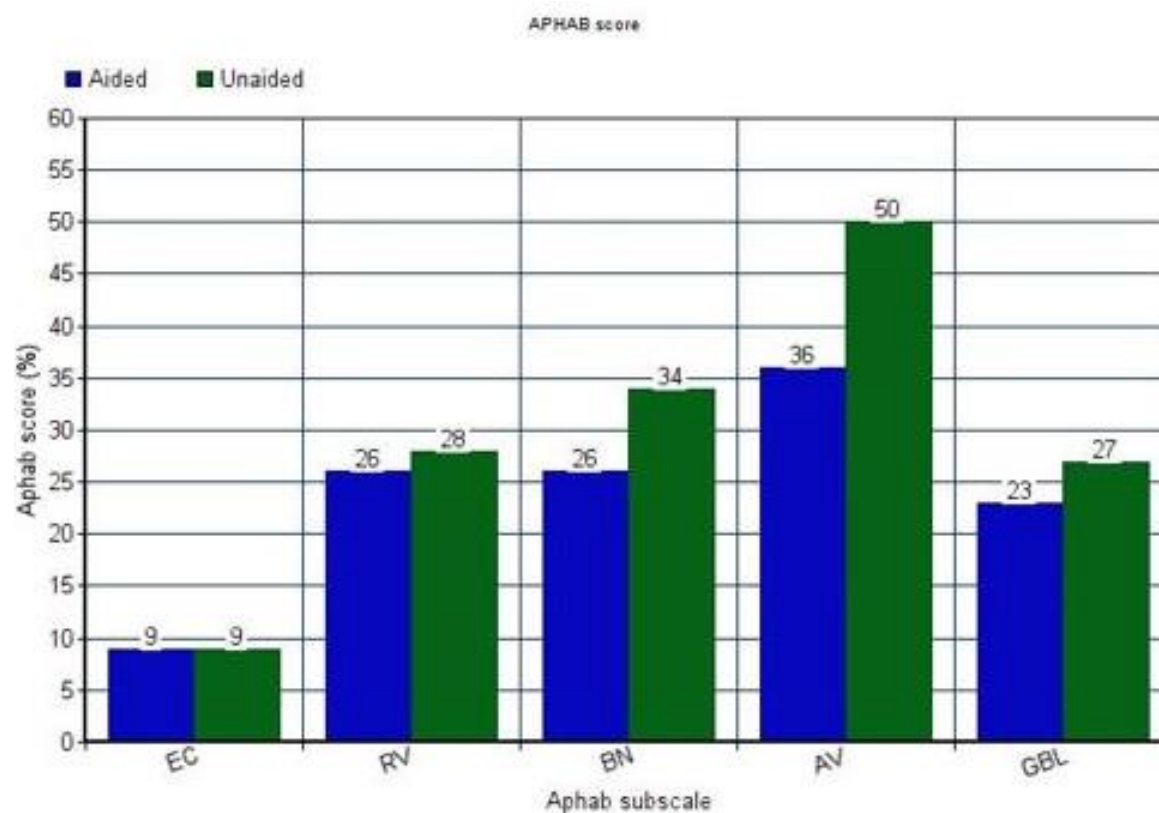


Figure 2.

