Human Reproduction vol.15 no.8 pp.1727–1733, 2000

Sperm motility index: a quick screening parameter from sperm quality analyser-IIB to rule out oligo- and asthenozoospermia in male fertility study

C.Martínez[1], C.Mar[1,3], M.Azcárate[1], P.Pascual[1], J.M.Aritzeta[2] and A.López-Urrutia[1]

[1]Laboratorio de Bioquímica and [2]Servicio de Ginecología, Hospital Galdakao, Barrio Labeaga, 48960 Galdakao, Vizcaya, Spain

[3]To whom correspondence should be addressed at: Laboratorio de Bioquímica, Hospital Galdakao. Barrio Labeaga, 48960 Galdakao, Vizcaya, Spain. E-mail: cmar@hgda.osakidetza.net

The aim of this study was to evaluate the sperm quality analyser (SQA)-IIB, a new automated sperm analyser, and to compare its results with those obtained with a method based on the World Health Organization recommendations. Eighty-nine unprocessed semen samples and 53 selected sperm suspensions were analysed. Concentration, motility and morphology were evaluated using the routine laboratory method. The SQA-IIB measured the sperm motility index (SMI) and estimated the previously mentioned parameters. In the imprecision assay a maximal coefficient of variation (CV) of 18.8% was found. A semen sample with immunological factor showed a CV of 75.75%, which invalidates its use for these types of samples. A good correlation was obtained between SMI and concentration of progressively motile spermatozoa (CPMS) (r = 0.87), and a fair correlation with the other parameters. There was no statistically significant correlation between both methods for normal sperm morphology. The sensitivity and specificity of the SMI test in relation to CPMS were 96 and 84% respectively, for an SMI threshold value of 160. The results obtained make the SQA-IIB a good screening test to rule out oligozoospermia and asthenozoospermia when studying the male factor in the sterility outpatient clinics. However, the results suggested that it is not a valid method to evaluate morphology.

Key words: automated semen analysis/semen quality/sperm motility index/sperm quality analyser

Introduction

In the semen analysis, concentration, motility and morphology measured traditionally with manual methods are still the most important parameters in the initial investigation of the male factor infertility. The most frequently used techniques are count chambers (e.g. haemocytometer and Makler chamber) to measure concentration, and wet preparation to measure motility. Both techniques are subject to a high variability. Although the concentration can be accurately assessed by volumetric techniques, motility and morphology are more subjective measurements. Sperm motility is influenced by temperature, the depth and nature of the chamber, and the subjective component when differentiating the grades of motility (Yeung *et al.*, 1997). On the other hand, assessment of morphology is affected by the fixation and staining techniques, the quality of the microscope and the observer's subjectivity. All these factors make these methods highly variable, as several internal and external quality control programmes have revealed (Chong *et al*., 1983; Jequier *et al*., 1983; Mortimer *et al*., 1986; Dunphy *et al*., 1989; Neuwinger *et al*., 1990; Matson *et al.*, 1995; Cooper *et al*., 1999).

In the last few years, several automated systems known as computer-assisted semen analysis (CASA) have become available. These systems, besides analysing the conventional parameters, supply a description of sperm kinematic movements (Boyers *et al*., 1989; Holt *et al*., 1994). A number of reports have demonstrated the prognostic and diagnostic value of these systems (Aitken *et al*., 1985; Feneux *et al*., 1985; Jeulin *et al*., 1986; Barratt *et al*., 1993; Aitken *et al*., 1994; MacLeod and Irvine, 1995). However, CASA instruments are not ready-to-use robots, and their reliability depends largely on the training, ability and experience of the user. In addition, the high cost of this equipment places it out of reach of most routine laboratories (Knuth *et al*., 1987; Comhaire *et al*., 1992; Holt *et al*., 1994; Kraemer *et al*., 1998).

The sperm quality analyser (SQA) is a simple device with no training requirements that performs an indirect analysis of sperm movement. The SQA has a photoelectric cell that detects the optic density fluctuations caused by the motility of spermatozoa. The analogue signal registered is converted digitally to provide the sperm motility index (SMI) value (Bartoov *et al*., 1991), which is affected by the number of spermatozoa and by the type of motility. Recently, a new version of the same device has appeared (SQA-IIB), incorporating a series of algorithms to calculate the traditional parameters of semen assessment on the basis of SMI measured value. There are several evaluations of the first model (Johnston *et al*., 1995; Shibahara *et al*., 1997; Mahmoud *et al*., 1998) comparing SMI parameter with the traditional parameters and the result of several assisted reproduction techniques. At present, only one evaluation of this new model has been reported (Makler *et al*., 1999) where the three parameters obtained from the traditional method and the SQA-IIB were compared. The aim of the current study was to evaluate this new model and to study its applicability to basic semen analysis, which has not been done yet.

Materials and methods

Semen specimens

Eighty-nine semen specimens and 53 Percoll selected sperm suspensions obtained from patients presenting to the sterility outpatient

Table I. Semen characteristics and sperm quality analyser (SQA)-IIB parameters as determined for unprocessed semen and selected spermatozoa

	Semen (n = 89)		Selected spermatozoa[a] (n = 53)	
	Median	Range	Median	Range
SQA-IIB				
SMI	204	0–497	485	40–581
Concentration ($\times 10^6$/ml)	76	0–195		
Motility (%)	51	0–82		
Normal (%)	34	0–52		
SQA-CPMS ($\times 10^6$/ml)	38.7	0–160		
Laboratory method				
CPMS ($\times 10^6$/ml)	25.8	0–79.2	46.9	2.4–208
Concentration ($\times 10^6$/ml)	65.8	0.24–290	80	6–270
Motility (%)	36.8	0–66.2	63.4	22–93.9
Normal (%)	15.7	2–37	n/a	n/a

[a]In the study of selected sperm suspensions the manufacturer only recommends the use of SMI.
SMI = sperm motility index; SQA-CPMS = concentration of progressively motile spermatozoa calculated from SQA-IIB; CPMS = concentration of progressively motile spermatozoa; n/a = not available.

clinic of the Galdakao Hospital between February and May 1999 were analysed. Semen specimens were obtained by masturbation after 3–7 days of sexual abstinence, and were analysed within 2 h of collection.

Semen analysis

After semen liquefaction for 30 min, sperm concentration, motility and morphology were determined at room temperature. Selected sperm suspensions were also analysed after the preparation process.

Sperm concentration and motility were measured objectively by means of the multiple exposure photographic method (MEP) described by Makler (Makler *et al*., 1984), using a phase contrast microscope, stroboscope and Polaroid photographic camera. The integration of photographs was done with the Andros software (Micron Espana, Barcelona, Spain) on digitized tablet connected to a computer. The Andros software is presented as a menu with nine options. With the aid of a digital pencil the number of motile and immobile spermatozoa and the trajectories of motile spermatozoa were entered. The semen volume and the number of counted squares are then introduced in the corresponding option in order for the Andros system to calculate the following data: effective distance (ED) mean/s, maximum and minimum ED, average velocity, index of directionality and percentage of motility grades a, b, c and d. Criteria for the different grades of sperm motility were established as a function of the ED/s: grade a (>26 μm/s), grade b (16–26 μm/s), grade c (<16 μm/s) and grade d (immobile) (Arán *et al*., 1990). The derived variable 'concentration of progressively motile spermatozoa' (CPMS) was calculated by multiplying the sperm concentration by the sum of motility grades a and b (progressive motility) expressed as percentages.

Morphology was evaluated on air-dried smears, fixed and stained by the quick-stain technique (Diff Quick; Quick-Panoptic, Amposta, Spain). World Health Organization criteria (WHO, 1992) were used to consider a spermatozoon as morphologicaly normal or abnormal. The result was expressed as percentage of spermatozoa with normal morphology examining at least 200 spermatozoa.

Sperm preparation

Semen was centrifuged at 200 *g* for 15 min through discontinuous Percoll gradients (40/80%) (Pharmacia, Uppsala, Sweden) and washed with Ham's F-10 medium (Biochrom), Berlin, Germany) supplemented with bovine serum albumin (BSA; Merck, Darmstadt, Germany). The spermatozoa were resuspended in 0.5 ml Ham's F-10 medium/BSA.

Sperm motility index determination

SMI determinations were performed at room temperature after routine analysis using the sperm quality analyzer (SQA-IIB; Medical Electronic Systems Ltd, Migdal Haemed, Israel). The semen sample was aspirated into a specifically designed capillary tube and then introduced into the analyser. The SQA has a photoelectric cell that detects the variations in optical density (OD) caused by the motility of spermatozoa. The SQA does not analyse the morphological defect (head problem, tail problem, acrosome staus, etc.). It only indicates what percentage of spermatozoa is normal. This is done not directly but through analysis of motion, i.e. if cell metabolism (energy) seems normal but motion is not progressive (circular, zig-zags, shaking only, etc.), the unit concludes that there is some defect in morphology. The measurement is performed over a 40 s period comprising four 10 s measurement periods, offering a mean of these four readings as a final result of SMI.

The new version (SQA-IIB) integrates a series of mathematical algorithms supplying the total sperm concentration, percentage of progressive motility, percentage of normal forms and the total functional sperm concentration (TFSC). The only parameter measured was the SMI, while the other four parameters are calculated. In order to compare the concentration of progressively motile spermatozoa obtained by two methods, we calculated SQA-CPMS multiplying sperm concentration by percentage of progressive motility provided by SQA-IIB.

According to the manufacturer's instructions semen samples with SMI <80 were abnormal, 80–160 were doubtful and >160 were normal. With SMI readings of <20, corresponding to very low quality semen, the SQA-IIB did not provide the parameters sperm concentration, percentage of progressive motility and normal morphology.

Intracapillary imprecision assay

In order to evaluate the stability of readings within the same capillary tube, six samples with different quality semen were analysed (samples 1 to 6) in 2 min intervals, repeating the measurement 20 consecutive times.

Table II. Intracapillary imprecision for six different semen samples

	Semen sample					
	1 Mean (CV)	2 Mean (CV)	3 Mean (CV)	4 Mean (CV)	5 Mean (CV)	6 Mean (CV)
SMI	51 (8.9)	146.9 (11.3)	269.8 (5.4)	365.2 (3.9)	458.8 (4.7)	148.2 (75.8)
Concentration ($\times 10^6$/ml)	15.2 (11.9)	54.3 (8.3)	95.8 (7.3)	147.2 (5.1)	182 (4.1)	54.7 (80.2)
Motility (%)	19.9 (10.8)	43.85 (3.25)	58.6 (3.5)	69.5 (2)	78.4 (2.7)	41.3 (37.9)
Normal (%)	17.5 (2.9)	28.9 (4.5)	40.8 (3.4)	46.3 (1.4)	50.3 (2)	27.1 (36.9)
TFSC ($\times 10^6$/ml)	14.5 (12.6)	113.9 (15.9)	390.3 (11.7)	745 (8.2)	996.8 (1)	163.4 (151.4)

[a]Sample affected by immunological factor.
CV = coefficient of variation; SMI = sperm motility index; TFSC = total functional sperm concentration.

Intercapillary imprecision assay

Three semen samples (A, B and C), with low, medium and high values of SMI, were analysed, assaying 20 different capillary tubes in each case.

Statistical analysis

A descriptive table was printed to show the median and range of the data obtained from the 89 semen samples and the 53 Percoll selected spermatozoa using the two methods compared. The imprecision study of the measurements performed by the SQA-IIB both intracapillary and intercapillary included the mean and coefficient of variation (CV) for each parameter. In the comparison study between methods, linear regression analysis was used to compare SMI with CPMS from the laboratory method. On the other hand, the Spearman correlation coefficient was applied to study the relationship between the studied parameters using the laboratory method and the SQA-IIB. Two-by-two tables were used to group semen samples according to the SMI test in relation to CPMS, and the sensitivity and specificity of the new method were determined.

Results

Table I describes semen characteristics and SQA-IIB parameters found in the 89 patients, as well as in the 53 Percoll selected sperm suspensions, showing the median and range.

Imprecision

The mean and coefficient of variation (CV) obtained for each of the six semen samples analysed in the intracapillary imprecision assay are shown in Table II. Excluding semen sample number 6, the coefficients of variation ranged from 1.4 to 15.9%. This last semen sample showed an immunological factor with immunobead test (IBT) positive for immunoglobulin (Ig)G (30%) and IgA (87%), interfering in SMI measurement and producing CV values from 36.9 to 151%. Figure 1 shows the 20 SMI readings for these six semen samples. In the intercapillary imprecision assay three semen samples with low (mean = 33), medium (mean = 143) and high (mean = 294) SMI values were analysed assaying 20 different capillary tubes in each case. CV obtained for SMI were 7.7, 18.8 and 17%, respectively. Results including all parameters are shown in Table III.

Method comparison

Table IV shows the correlation coefficients obtained when the SQA-IIB parameters and those from the traditional laboratory method were compared for the 89 semen specimens studied.

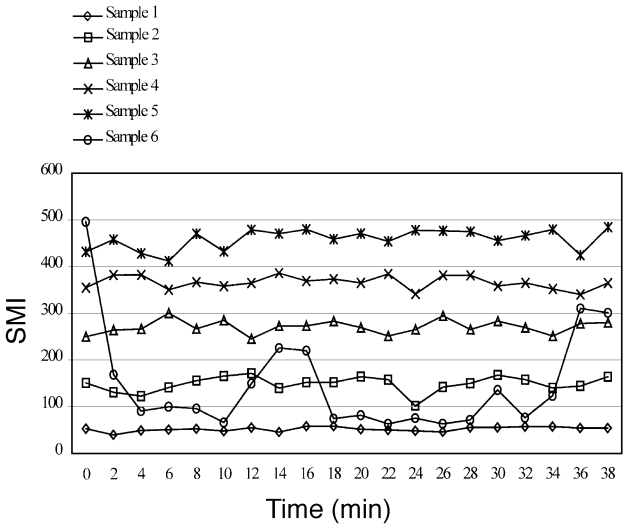

Figure 1. The sperm motility index (SMI) values for 20 readings performed in the intracapillary imprecision assay for the six semen samples as in Table II. Semen sample 6 showed an immunological factor (IBT positive for immunoglobulins G and A).

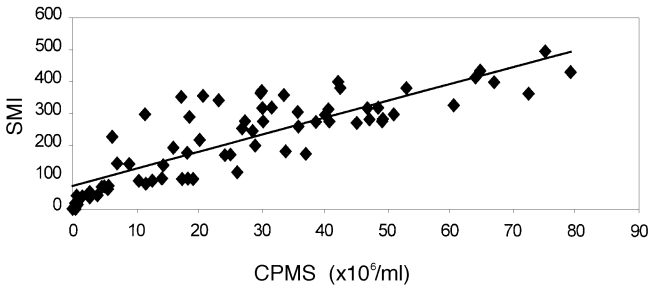

Figure 2. Correlation study of concentration of progressively motile spermatozoa (CPMS) from laboratory method and sperm motility index (SMI) from sperm quality analyser (SQA)-IIB obtained from the 89 semen specimens studied. The regression line is plotted (CPMS = 0.13×SMI – 1.54, R^2 = 0.732).

A comparison between the concentration of progressively motile spermatozoa (CPMS) and SMI was performed, obtaining the best correlation, r = 0.87 [95% confidence interval (CI): 0.82–0.92]. When studying this same relationship with Percoll selected sperm suspensions, two distinct populations were observed, the first one with CPMS values $\leq 75 \times 10^6$/ml, where a correlation coefficient of 0.86 (95% CI: 0.73–0.93) was

Table III. Intercapillary imprecision for three different semen samples

	Semen sample		
	A Mean (CV)	B Mean (CV)	C Mean (CV)
SMI	32.8 (17)	142.8 (18.8)	294.4 (7.7)
Concentration ($\times 10^6$/ml)	8 (22.6)	52.6 (18.5)	108.1 (10.6)
Motility (%)	12.1 (20.6)	42.9 (8.1)	61.8 (4.7)
Normal (%)	15.1 (5.2)	28.2 (10.6)	42.5 (3.3)
TFSC ($\times 10^6$/ml)	8.2 (22.6)	107.2 (35.2)	473.2 (16.6)

CV = coefficient of variation; SMI = sperm motility index; TFSC = total functional sperm concentration.

Table IV. Correlation between parameters from laboratory method and sperm quality analyser (SQA)-IIB (n = 89)

SQA-IIB	Manual method	r[a]	P
SMI	CPMS	0.87	<0.001
SMI	Concentration	0.75	<0.001
SMI	Motility	0.64	<0.001
SMI	Normal	0.45	0.006
Concentration	Concentration	0.75	<0.001
Motility	Motility	0.64	<0.001
Normal	Normal	0.37	0.03
SQA-CPMS	CPMS	0.87	<0.001

[a]Spearman test.
SMI = sperm motility index; SQA-CPMS = concentration of progressively motile spermatozoa calculated from SQA-IIB; CPMS = concentration of progressively motile spermatozoa; n/a = not available.

obtained, and another one for values $>75\times10^6$/ml in which the correlation was lower and not statistically significant (r = 0.39).

The linear regression analysis of the relationship between SMI and CPMS indicated that 73.2% of the variance of SMI could be accounted for by the CPMS alone. The linear regression was: CPMS = 0.13×SMI – 1.54, R^2 = 0.732.

In order to study the equivalence between CPMS and SQA-CPMS, correlation and linear regression analysis were performed. A correlation coefficient of 0.87 (95% CI: 0.82–0.92) was found and the linear regression was: CPMS = 0.41×(SQA-CPMS) + 6.1, R^2 = 0.714.

Detection limit and linearity

In five semen samples the SQA-IIB showed an SMI value less than 20: two cases with zero value were azoospermic and in the other three, for an SMI equal to 0, 13 and 18, CPMS values of 0.45, 0.78 and 0.42×10^6/ml respectively (mean = 0.54×10^6/ml) were obtained. Establishing the limit at 0.54×10^6/ml CPMS we found only one case with a value lower than this limit (0.42×10^6/ml) where the SMI reading was 22, very close to the reading limit of the SQA-IIB.

Since high correlation between SMI and CPMS with Percoll selected spermatozoa disappeared with values higher than 75×10^6/ml, a limit of 75×10^6/ml for CPMS was established corresponding to an SMI of 500. A SMI value higher than 500 was not found in unprocessed semen and only one semen sample had a CPMS value of 79.2×10^6/ml with an SMI of 432. In the case of Percoll selected spermatozoa, five cases out of 31 with CPMS lower than 75×10^6/ml had an SMI value higher than 500, and otherwise only two out of 21 cases with CPMS higher than 75×10^6/ml had an SMI value lower than 500.

Table V. Sensitivity and specificity of sperm quality analyser-IIB

	SMI	CPMS ($\times10^6$/ml)	
		<10.4	⩾10.4
Criteria 1	<80	20	1
	⩾80	5	63
Criteria 2	<160	24	10
	⩾160	1	54

SMI = sperm motility index; CPMS = concentration of progressively motile spermatozoa.

Diagnostic usefulness of SMI

Because of the excellent correlation existing between SMI and CPMS, the diagnostic usefulness of the SMI was studied. The population was divided into two groups using as threshold value a CPMS of 10.4×10^6/ml, the value corresponding to the 10th percentile of the reference values established in our laboratory analysing semen from men with proven fertility within 2 years before the analysis.

Table V shows the two-by-+two tables grouping the values using threshold values recommended by the manufacturer (80 and 160). For an SMI threshold value of 80, the sensitivity was 80% and the specificity was 98%. When a threshold value of 160 was used, the sensitivity increased to 96% and the specificity remained at 84%.

Discussion

One of the main problems encountered with manual methods is the high imprecision they are subjected to. This is, to a great extent, because of the variability and subjectivity introduced by the observer. It was demonstrated that up to 57% of the variation between duplicate determinations by the same technician was due to the technician himself (Freund and Carol, 1964).

Several quality control programmes implemented in the last 10 years revealed that the results were highly scattered among different laboratories, among different technicians from the same laboratory and even within the same technician. Thus, very different CV are found in the literature. In intra- and inter-technician studies, sperm concentration ranged from 6 to 12%, motility from 5.5 to 28.5% and morphology from 5.1 to 27.7%. Comparing different spermatozoa counting chambers, CV moved from 4.3 to 26.3% and in external quality control studies CV from 8 to 37% were found. The lowest CV were found in intra-technician studies, related to observer ability and training. Higher values in inter-technician studies, reaching clinically significant differences were found. Also, unacceptably high values were observed in multicentric and external quality control studies that rendered the results from

different laboratories not interchangeable (Dunphy *et al*., 1989; Menkveld *et al*., 1990; Neuwinger *et al*., 1990; Cooper *et al*., 1992; Matson *et al.*, 1995; Mahmoud *et al*., 1997).

A high variation was found in CASA systems, mostly because these results depended on the user training and expertise. Clements (Clements *et al.*, 1995) obtained for the Hamilton–Thorn motility (HTM) analyser a coefficient of variation for concentration of 9.5%, for fast motility 11.8% and for slow motility 67.3%.

Our experience with the SQA-IIB showed, in the imprecision assay with a single capillary tube, a good repeatability for the SMI value; the CV ranged from 3.9 to 11.3%, values that also remained low for the calculated parameters included: sperm concentration, percentage of motile spermatozoa and morphology. These low CV found in the intracapillary assay demonstrated the sample stability in the capillary for at least 40 min. One of the six semen samples showed a very high variation in the readings performed in the same capillary tube, with a CV value for SMI of 75.7%. This sample had an immunological factor causing instability in the measurements. Every basic semen study has to include a test to investigate the presence of antisperm antibodies (WHO, 1992) and, if a positive result is observed, the use of the SQA-IIB would be ruled out.

In the intercapillary study, slightly higher CV values were found for the SMI: from 7.7 to 18.8%. This imprecision resulted from the variation due to the instrument itself and that introduced by the user when charging the capillary tube; however, it did not reach the high variations published for the traditional parameters and methods (Matson, 1995; Johnson *et al*., 1996; Mahmoud *et al*., 1997). The results for overall imprecision in the current study, including that from intra-assay, inter-assay and inter-observer, were 7.4% for sperm concentration (mean = 91.6×10^6/ml), 13.41% for progressive motility (mean = 35.64%) and 16.13% for CPMS (mean = 32.72×10^6/ml), which corresponded to a high SMI value.

The linearity of the SQA-IIB with Percoll selected spermatozoa was studied, as a way to achieve high concentrations of progressively motile spermatozoa. It was found that this limit was achieved with a CPMS value equal to 75×10^6/ml corresponding to an SMI value of 500. With higher values the excellent correlation disappeared ($r = 0.39$). Since similar correlation coefficients were found between SMI and CPMS in unprocessed semen and selected spermatozoa ($r = 0.87$ and 0.86 respectively), the same value was applied to unprocessed semen. None of the 89 unprocessed semen samples had an SMI value higher than 500 and only one case exceeded the CPMS value of 75×10^6 ml, which was 79.2×10^6/ml, very close to the limit. The results were different to those of Bartoov (Bartoov *et al*., 1991) who published a linearity corresponding to 40×10^6/ml motile cells without specifying the motility type. The data presented here established that the SQA-IIB readings were linear up to SMI values of 500 with selected spermatozoa. However, it would be necessary to confirm this linearity limit with unprocessed semen samples with high CPMS.

Another subject of the evaluation was the detection limit. A SMI limit of 20 is given by the manufacturer. With SMI values lower than 20 the remaining parameter values are zero. SMI readings between 0 and 20 would indicate the presence of scarce motile spermatozoa, as it was observed in two cases showing SMI of 18 and 13 with CPMS of 0.42 and 0.78×10^6/ml respectively. SMI readings equal to zero would correspond to an absence of motile spermatozoa or azoospermia, a situation that was not fulfilled in one case in which a CPMS value of 0.45×10^6/ml was found for an SMI equal to zero. This would invalidate the use of the SQA-IIB in post-vasectomy controls, since there can be cases with the presence of spermatozoa and a zero SMI result; however, the manufacturer noted that in these cases repeating the reading up to five times in the same capillary tube, at least one reading would be different to zero. The opposing case was not found in this study, i.e. absence of spermatozoa and an SMI value not equal to zero. With the five semen samples with an SMI value lower than 20 a CPMS limit of 0.54×10^6/ml was established, below which the SQA-IIB would not be able to distinguish the presence or absence of motile spermatozoa. The number of semen samples used to establish this limit was very low, but more cases were not available, so more data would be required in order to ascertain this with more precision.

The correlation study performed on unprocessed semen samples between the SQA-IIB and the laboratory method showed that the best relationship was established between the SMI and CPMS ($r = 0.87$), slightly lower than the correlation found by other authors ($r = 0.92$) (Johnston *et al*., 1995). This high correlation would be expected since the SQA-IIB measures moving spermatozoa.

When comparing SMI with sperm concentration and progressive motility percentage lower correlation coefficients were found, 0.75 and 0.64 respectively. This was due to the fact that in both parameters non-motile spermatozoa were involved and the SQA-IIB system was unable to detect them. Similar correlation coefficients were found when comparing sperm concentration and percentage of progressively motile spermatozoa with both methods ($r = 0.75$ and 0.64). This would also be expected since the SQA-IIB calculates both parameters from the SMI, repeating the same concentration and percentage of motility values for the same SMI value. However, the experience in the andrology laboratory shows that it is not possible to establish a mathematical relationship between concentration and motility. In relation to morphology the correlation coefficients found were drastically reduced, $r = 0.45$ with SMI and $r = 0.37$ between both methods. So, the SQA-IIB was found to be unsuitable for obtaining the main parameters in the analysis of semen, i.e. spermatozoa concentration, motility and morphology.

The study between the derived variables CPMS and SQA-CPMS showed a good correlation ($r = 0.87$), but the linear regression analysis demonstrated no identity between them, with a slope of 0.41. So, the same parameters were not being measured. The SQA-CPMS would have a similar significance as the SMI had; however, it might introduce confusion with the true CPMS parameter.

The results of the current study agreed with those obtained by Makler (Makler *et al*., 1999), who observed important deviations among the three traditional parameters measured

by both methods and rejected the use of SQA-IIB in routine semen analysis. The only objective of Makler *et al*. (1999) was to compare the three main sperm parameters obtained according to the standards of the WHO and those measured by the SQA-IIB, but they did not go any further in evaluating SQA-IIB. Seventeen out of 43 semen samples studied by Makler were manipulated. The manufacturer states that with these types of samples the only parameter to be considered is the SMI. In the current study technical characteristics of SQA-IIB were evaluated and 89 unprocessed semen samples compared. The satisfactory imprecision and the good correlation observed between SMI and CPMS encouraged further investigation its clinical usefulness in the male factor study.

The sensitivity and specificity of both SMI threshold values supplied by the manufacturer (80 and 160) were investigated. Thus a CPMS threshold value of 10.4×10^6/ml was used, the value corresponding to the 10th percentile of reference values established in our laboratory from semen from men with proven fertility within 2 years before the analysis. Considering the SMI value of 80, 80% sensitivity and 98% specificity were obtained, values different from those obtained by Bartoov (Bartoov *et al*., 1991), who found a 93% sensitivity and 85.5% specificity, but using a threshold value for sperm concentration of 20×10^6/ml. Using the SMI value of 160 a 96% sensitivity and 84% specificity was achieved in the current study. Therefore, using 160 as threshold value to differentiate fertile and subfertile semen, only one semen with CPMS of 7.6×10^6/ml remained misclassified (Table V). This suggested that it would only be necessary to assess sperm concentration and motility by microscopy in those semen samples showing SMI lower than 160. CPMS is a parameter that can be used to differentiate between fertile and subfertile semen (Hinting *et al*., 1988). It has been related to success in intrauterine insemination (Brasch *et al*., 1994). Also it has been demonstrated to be able to discriminate between in-vitro fertile and unfertile semen (Comhaire *et al*., 1988). CPMS was also recommended by the WHO manual in its latest edition (WHO, 1999) as derived variable. All this, together with the high correlation found between SMI and CPMS, and the good performance of the instrument, permits consideration of the SMI value as a screening test for the global measurement of concentration and progressive motility of spermatozoa.

In conclusion, the SQA-IIB was a very easy to use, manageable and cheap device, that required no trained personnel, was not time consuming and showed a good performance. The SMI parameter allowed discrimination, with high sensitivity, between fertile and subfertile semen samples according to CPMS. For all these reasons, it is concluded that SMI was a good screening test to rule out oligozoospermia and asthenozoospermia in the male factor study in the context of sterility clinics, requiring the assessment of sperm concentration and motility by microscopy in all those semen samples showing an SMI value lower than 160 and higher than 500. It should be noted that it was not a valid method for evaluating morphology, in which case WHO methods would have to be followed (WHO, 1999).

Acknowledgements

The authors thank J.M.Quintana (Unidad de Epidemiología Clínica, Hospital Galdakao) for his contribution in preparing this manuscript, and L.Bassas (Laboratorio de Andrología y Reproducción, Fundación Puigvert) for his critical review. SQA-IIB and capillary tubes were kindly provided by J.Solsona (IZASA S.A.).

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Received on January 26, 2000; accepted on April 26, 2000