RESULTS

One hundred and twenty patients were randomly allocated into three equal groups (each 40 patient); group I (propofol TIVA), group II (propofol-ketamine TIVA) and group III (isoflurane inhalational anaesthesia). Each group was divided into two equal subgroups (each 20 patient); subgroups A (IA & IIA & IIIA), where the hypnotic drug concentration (propofol or isoflurane) was adjusted to keep the BIS between 40 and 60 during surgery, and subgroups B (IB & IIB & IIIB), where the hypnotic drug concentration was adjusted according to the standard clinical practice.

Demographic data:

There were no significant statistical differences between subgroup IA and subgroup IB as regard age ,sex ,weight and the durations of anaesthesia.

Table(7-1): Demographic characteristics in propofol subgroups (IA&IB)

		N	Mean	Std. Deviation	t	P
Age (years**)**	***Subgroup IA***	**20**	**42.80**	**10.606**	**1.3**	**>0.05**
	Subgroup IB	**20**	**37.90**	**12.794**		
Wt (Kg**)**	***Subgroup IA***	**20**	**76.75**	**7.656**	**1.2**	**>0.05**
	Subgroup IB	**20**	**73.20**	**10.788**		
Duration of anaesthesia (Min**)**	***Subgroup IA***	**20**	**60.00**	**18.445**	**0.1**	**>0.05**
	Subgroup IB	**20**	**59.50**	**17.695**		
Sex (male **:** female**)**	***Subgroup IA***	**11:9**			**X^2**	**P**
	Subgroup IB	**10:10**			**0.1**	**>0.05**

There were no significant statistical differences between subgroup IIA and subgroup IIB as regard age ,sex ,weight and the durations of anaesthesia.

Table(7-2):Demographic characteristics in propofol-ketamine subgroups (IIA &IIB)

		N	Mean	Std. Deviation	t	P
Age(years)	***Subgroup IIA***	**20**	**39.35**	**11.389**	**---**	**----**
	Subgroup IIB	**20**	**39.35**	**11.226**		
Wt(Kg)	***Subgroup IIA***	**20**	**74.50**	**9.720**	**0.2**	**>0.05**
	Subgroup IIB	**20**	**75.00**	**9.177**		
Duration of anaesthesia(Min)	***Subgroup IIA***	**20**	**56.75**	**16.667**	**0.1**	**>0.05**
	Subgroup IIB	**20**	**56.55**	**17.813**		
Sex (male **:** female)	***Subgroup IIA***	**12:8**			**X^2**	**P**
	Subgroup IIB	**11:9**			**0.1**	**>0.05**

Also,there were no significant statistical differences between subgroup IIIA and subgroup IIIB as regard age, sex, weight and the durations of anaesthesia.

Table(7-3):Demographic characteristics in isoflurane subgroups (IIIA &IIIB)

		N	Mean	Std. Deviation	t	P
Age (years**)**	***Subgroup IIIA***	**20**	**39.75**	**11.986**	**0.3**	**>0.05**
	Subgroup IIIB	**20**	**40.70**	**10.687**		
Wt (Kg**)**	***Subgroup IIIA***	**20**	**73.25**	**9.358**	**0.6**	**>0.05**
	Subgroup IIIB	**20**	**71.50**	**10.013**		
Duration of anaesthesia(Min**)**	***Subgroup IIIA***	**20**	**59.05**	**18.426**	**0.2**	**>0.05**
	Subgroup IIIB	**20**	**57.80**	**17.573**		
Sex (male **:** female**)**	***Subgroup IIIA***	**9:11**			**X^2**	**P**
	Subgroup IIIB	**13:7**			**1.6**	**>0.05**

Anaesthetic drug consumption:

A highly significant reduction (**36.1%)** in propofol infusion rate was found in BIS-guided propofol subgroup (IA) compared to propofol subgroupIB (without BIS) [(***8.3*** ± ***0.81***) vs (***11.3*** ± ***0.89***) mg/kg/h , *P < 0.001*].Also there was a high significant reduction (**30.9%)** in propofol infusion rate in BIS- guided propofol-ketamine subgroup IIA compared to propofol-ketamine subgroup IIB (without BIS) [(***7.15*** ± ***0.62***) vs (***9.26*** ± ***0.61***) mg/kg/h, *P < 0.001*].

There was statistically high significant reduction (**36.8%**) in end tidal isoflurane concentration in BIS-guided subgroup (IIIA) compared to subgroupIIIB(without BIS) [(***0.95***± ***0.14***) vs (***1.27***± ***0.25***) **%** , *P < 0.001*].

Table(8-1): Different subgroups according to the consumption of anaesthetics:

Anaesthetic drugs	*Subgroups*	N	Mean	Std. Deviation	t	p	% change
Propofol (mg/kg/h)	***Subgroup IA***	**20**	**8.2970**	**.80963**	**11.3**	**<0.001**	**36.1%**
	Subgroup IB	**20**	**11.3390**	**.88804**			
	Subgroup IIA	**20**	**7.1470**	**.62294**	**10.9**	**<0.001**	**30.9%**
	Subgroup IIB	**20**	**9.2620**	**.60974**			
Isoflurane end-tidal concentration (%)	***Subgroup IIIA***	**20**	**.9525**	**.13969**	**4.9**	**<0.001**	**36.8%**
	Subgroup IIIB	**20**	**1.2700**	**.25288**			

The mean(SD) propofol infusion rate in BIS-guided propofol-ketamine subgroup IIA was lower (**16.9%**) than in BIS-guided propofol subgroup IA [(***7.15*** ± ***0.62***) vs (***8.3*** ± ***0.81***) mg/kg/h , *P < 0.001*] .Also , the mean(SD) propofol infusion rate in propofol-ketamine subgroup IIB(without BIS) was significantly lower (**21.5%**) than in propofol subgroup IB(without BIS) [(***9.26*** ± ***0.61***) vs (***11.3*** ± ***0.89***) mg/kg/h , *P < 0.001*]. So there was a reduction in propofol consumption in group II (propofol-ketamine) than in group I (propofol), which is statistically highly significant *(P < 0.001)*.

Table (8-2): Propofol infusion rates in group I &II.

		N	Mean	Std. Deviation	t	p	% change
Propofol (mg/kg/h)	***Subgroup IA***	**20**	**8.2970**	**.80963**	**5.4**	**<0.001**	**16.9%**
	Subgroup IIA	**20**	**7.1470**	**.62294**			
	Subgroup IB	**20**	**11.3390**	**.88804**	**8.3**	**<0.001**	**21.5%**
	Subgroup IIB	**20**	**9.2620**	**.60974**			

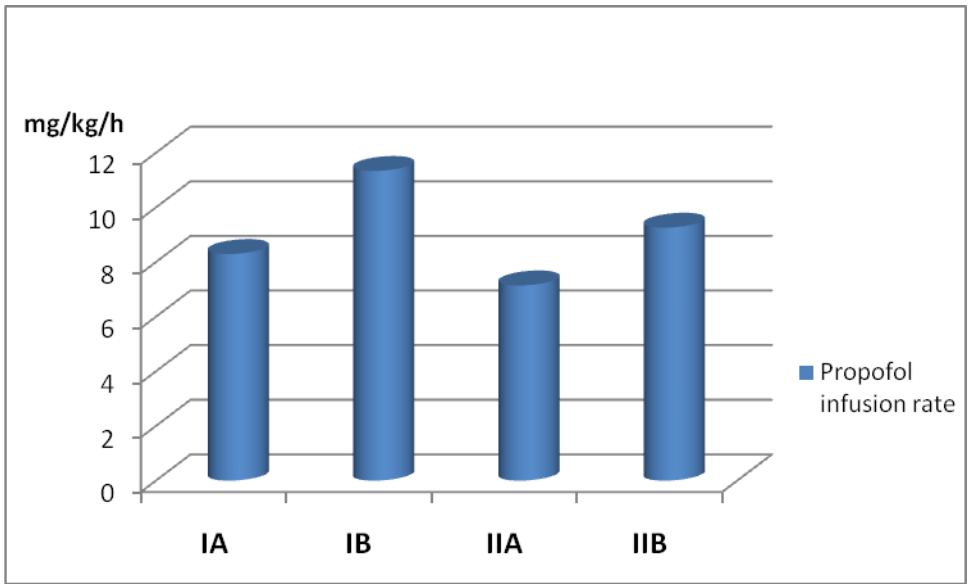

Fig. (28): Propofol infusion rates in group I&II.

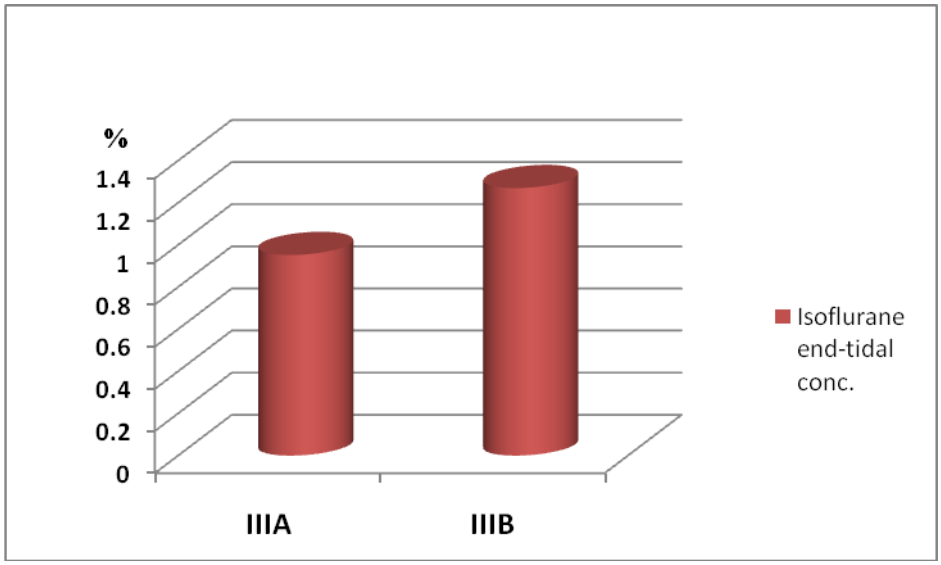

Fig. (29): Isoflurane end-tidal concentration in group III.

Hemodynamics:

In propofol group (I), mean arterial pressure (MAP) in subgroup A (with BIS) was higher than in subgroup B (without BIS) (***85.61*** vs ***78.09*** mmHg , *P < 0.001*). Also the heart rate (HR) in subgroup A was higher than in subgroup B (***74.32*** vs ***68.85*** bpm, *P < 0.001*), which is statistically highly significant *(P < 0.001)*.

In propofol-ketamine group (II), MAP in subgroup A (with BIS) was highly significantly lower than in subgroup B (without BIS) (***92.61*** vs ***98.16*** mmHg , *P < 0.001*). While HR was insignificantly lower in subgroup A than in subgroup B (***85.82*** vs ***87.44*** bpm, *P > 0.05*).

In isoflurane group (III), MAP in subgroup A (with BIS) was significantly higher than in subgroup B (without BIS) (***90.86*** vs ***86.90*** mmHg , *P < 0.001*). While HR was significantly lower in subgroup A than subgroup B (***76.38*** vs ***86.44*** bpm , *P < 0.001*), which is statistically highly significant *(P < 0.001)*.

Among the BIS subgroups (IA , IIA , IIIA) propofol subgroup (IA) had the lowest MAP and HR.

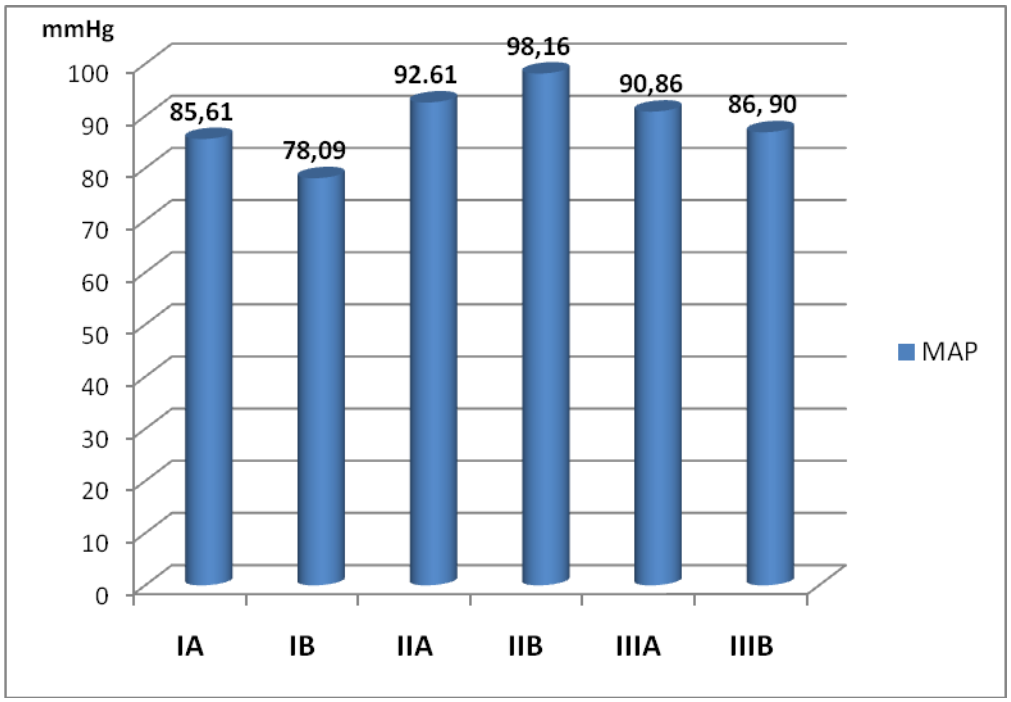

Fig.(30): Different subgroups according to the mean arterial blood pressure(MAP).

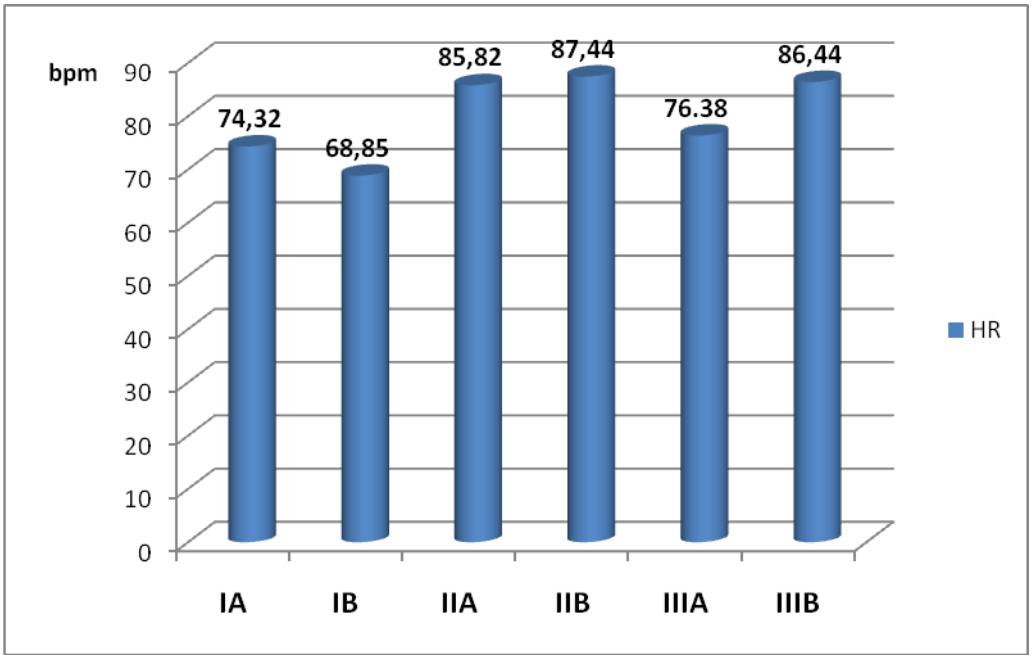

Fig.(31): Different subgroups according to the heart rate (HR).

Recovery profiles:

Spontaneous breathing times were significantly shorter in BIS subgroups (IA , IIA , IIIA) (***2.04 , 4.08 , 1.14*** min.) than in subgroups without aid of BIS information (IB , IIB , IIIB) (***4.95 , 6.01, 6.41*** min.) respectively, which is statistically highly significant (*P value < 0.001*) ,with the shortest time being in isoflurane subgroup IIIA(with BIS) .

Extubation times were significantly shorter in BIS subgroups (IA, IIA, IIIA) (***5.05, 6.995 , 2.63*** min.) than in subgroups without aid of BIS (IB , IIB , IIIB) (***7.02 , 9.98 , 9.05*** min.) respectively, which is statistically highly significant (*P value < 0.001*),with the shortest time being in isoflurane subgroup IIIA(with BIS).

Times to obey commands (eye opening to verbal command) were significantly shorter in BIS subgroups (IA , IIA , IIIA) (***8 , 12.55 , 6.24*** min.) than in subgroups without aid of BIS (IB , IIB , IIIB) (***9.93 , 15.65, 16.13*** min.) respectively, which is statistically highly significant (*P value < 0.001*) ,with the shortest time being in isoflurane subgroup IIIA(with BIS).

Times to achieve a modified Aldrete score ≥ 9, were significantly shorter in BIS subgroups (IA , IIA , IIIA) (***11.29 , 17.2 , 10.35*** min.) than in subgroups without aid of BIS (IB , IIB , IIIB) (***14.41 , 21.35 , 19.90*** min.) respectively, which is statistically highly significant (*P value < 0.001*), with the shortest time being in isoflurane subgroup IIIA (with BIS) .

All recovery times were determined at one-minute intervals from discontinuation of anaesthetics.

Table(9):Recovery profiles in propofol group I (IA & IB)

Recovery times (min)	Subgroup IA	Subgroup IB	t	p
Spontaneous breathing	2.04±0.48	4.95±1.26	9.6	<0.001
Extubation	5.05±0.69	7.02±0.76	8.6	<0.001
Obey commands	8±0.84	9.93±1.26	5.7	<0.001
Modified Aldrete≥9	11.29±1.17	14.41±1.28	8.1	<0.001

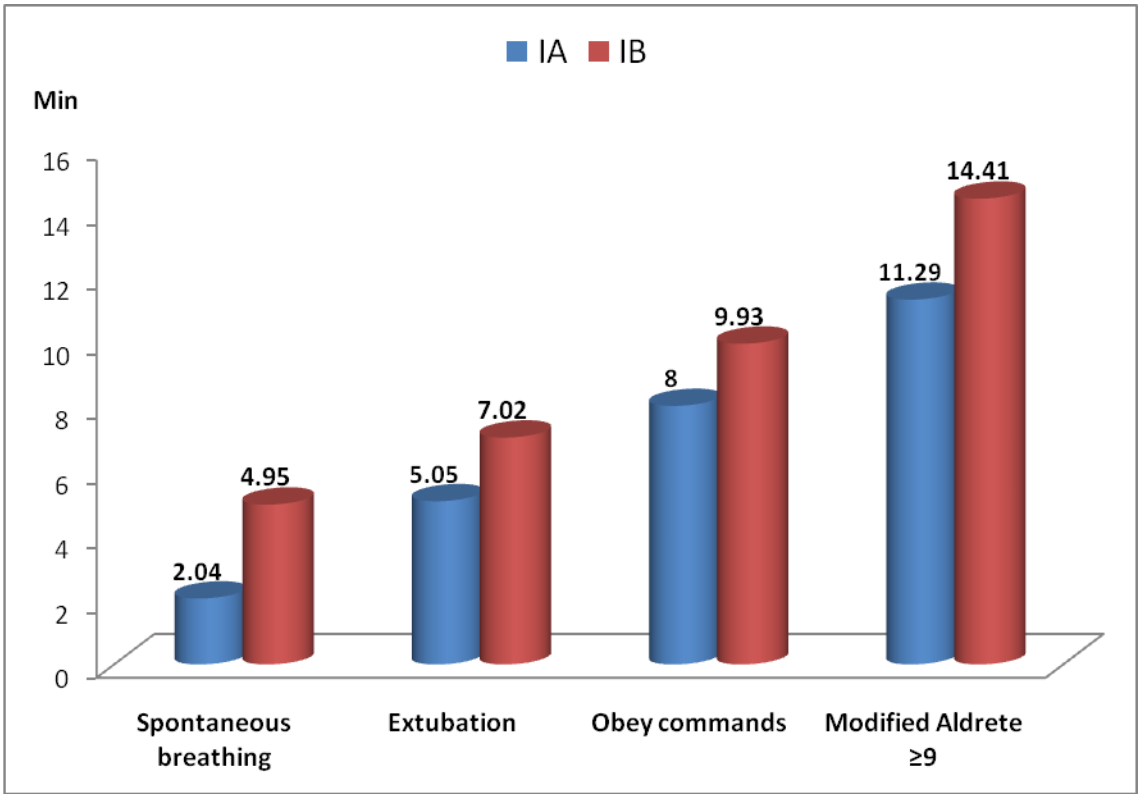

Fig. (32): Recovery profiles in propofol group I (IA & IB).

Table(10):Recovery profiles in propofol-ketamine group II(IIA &IIB)

Recovery times	Subgroup IIA	Subgroup IIB	t	p
Spontaneous breathing	4.075±1.12	6.005±0.69	6.6	<0.001
Extubation	6.995±0.77	9.975±0.9	11.2	<0.001
Obey commands	12.55±1.77	15.65±1.78	5.5	<0.001
Modified Aldrete≥9	17.2±1.37	21.35±1.98	7.7	<0.001

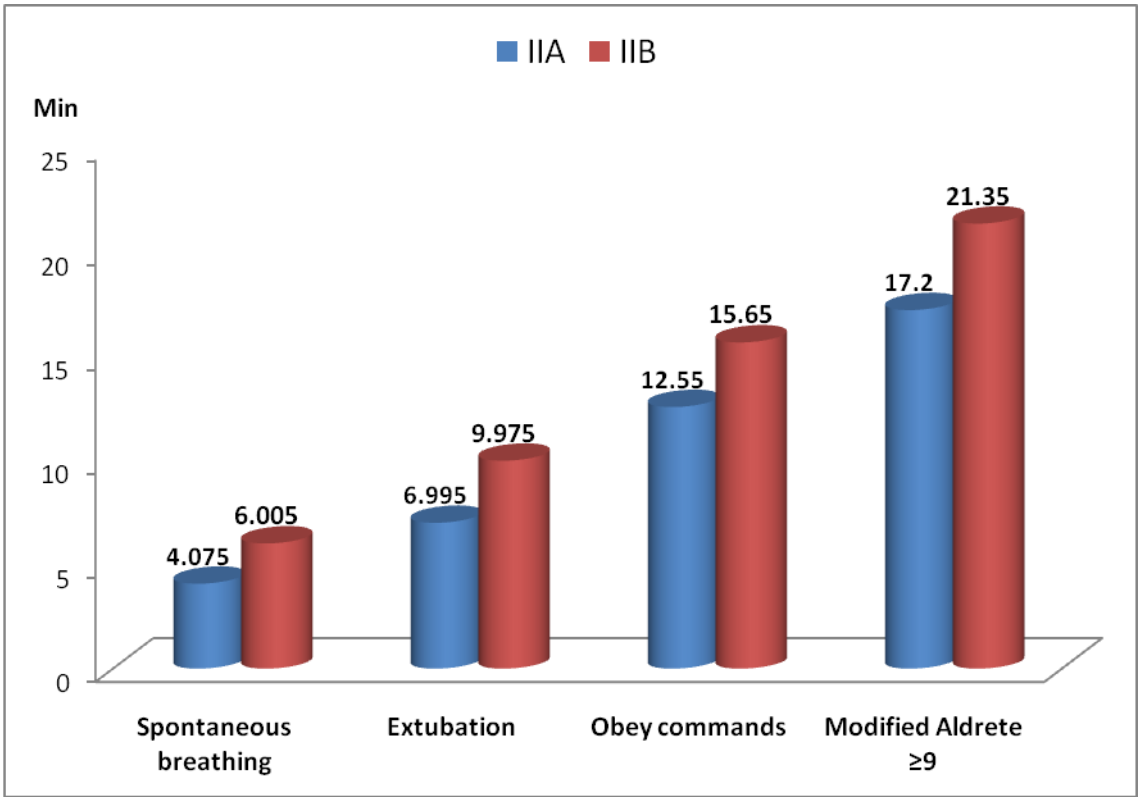

Fig. (33): Recovery profiles in propofol-ketamine group II(IIA &IIB).

Table(11):Recovery profiles in isoflurane group III (IIIA & IIIB).

Recovery times	Subgroup IIIA	Subgroup IIIB	t	p
Spontaneous breathing	1.14±0.44	6.41±0.74	27.4	<0.001
Extubation	2.63±0.69	9.05±1.11	22.01	<0.001
Obey commands	6.24±0.85	16.13±1.7	22.9	<0.001
Modified Aldrete≥9	10.35±1.06	19.9±2.62	15.1	<0.001

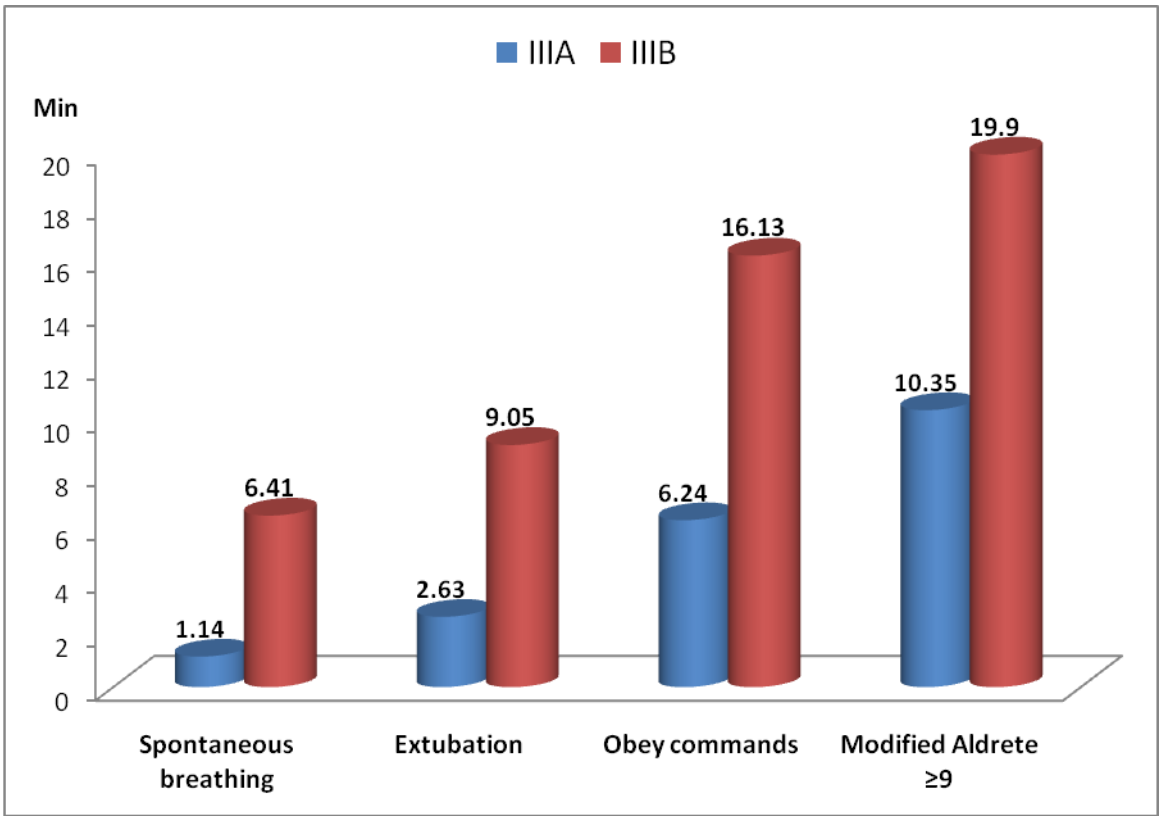

Fig. (34): Recovery profiles in isoflurane group III (IIIA & IIIB).

Table(12):Recovery profiles in BIS-guided subgroups(IA & IIA &IIIA)

Recovery times	Subgroup IA	Subgroup IIA	Subgroup IIIA	f	P
Spontaneous breathing	2.04±0.48	4.08±1.12	1.14±0.44	81.3	<0.001
Extubation	5.05±0.69	6.995±0.77	2.63±0.69	188.5	<0.001
Obey commands	8±0.84	12.6±1.77	6.24±0.85	139.6	<0.001
Modified Aldrete≥9	11.29±1.17	17.2±1.37	10.35±1.06	190.2	<0.001

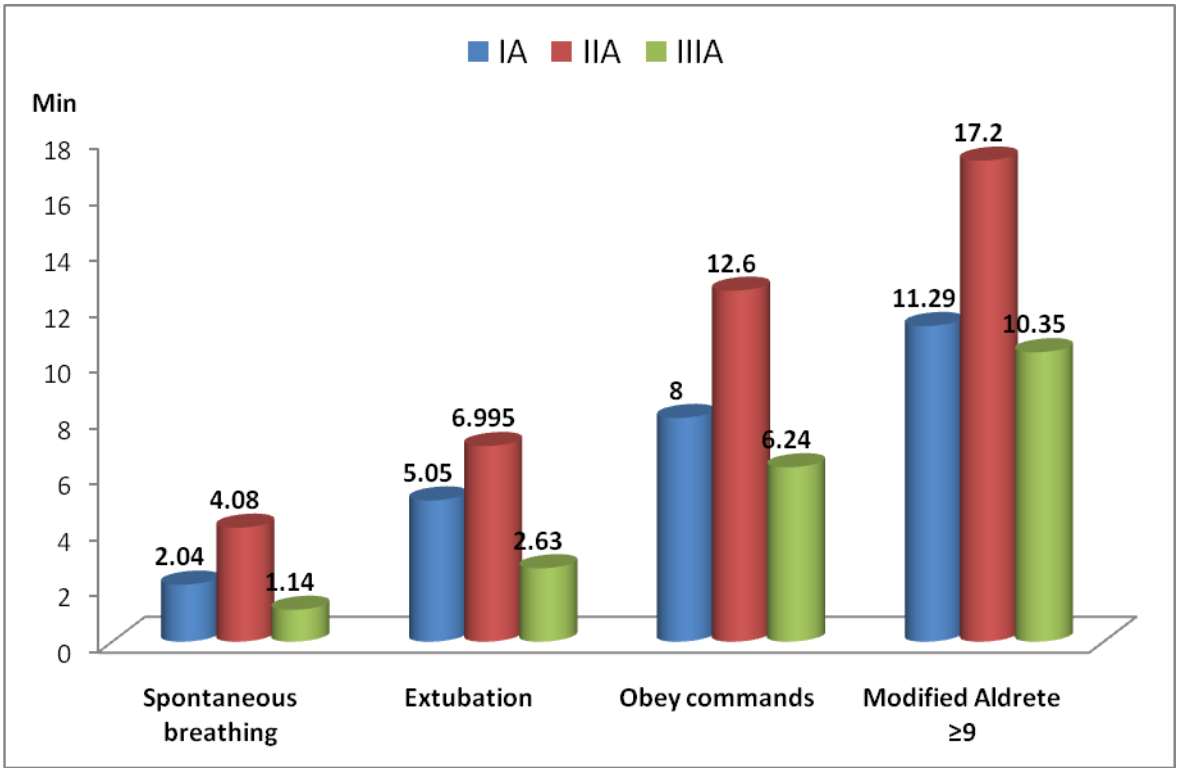

Fig. (35): Recovery profiles in BIS-guided subgroups(IA & IIA &IIIA).

Awareness:

Patients were questioned for recall of events, hearing vague sounds, feeling surgical instruments or dressing application, or dreaming, and we did not encounter any case of operation-related recall (awareness), in either subgroups.

Postoperative complications:

The incidence of postoperative nausea and vomiting in the first 24 h postoperatively , was lower in BIS subgroups; IA (***n= 1, 5%***) & IIA (***n= 0, 0%***) & IIIA (***n= 4, 20%***) than in subgroups without aid of BIS; IB (***n= 3, 15%***) & IIB(***n= 2, 10%***) &IIIB (***n= 7, 35%***) respectively, but these results did not reach a statistically significant value (*P value > 0.05*).The least incidence being in propofol-ketamine subgroup IIA(with BIS) ,and the highest incidence being in isoflurane subgroup IIIB (without BIS). None of the patients of all six subgroups had experienced any hallucinations.

Table (13): Different subgroups according to the postoperative data

	IA*(N=20)*	***IB****(N=20)*	***IIA****(N=20)*	***IIB****(N=20)*	***IIIA****(N=20)*	***IIIB****(N=20)*
Awareness	**0**	**0**	**0**	**0**	**0**	**0**
PONV	**1 (5%)**	**3 (15%)**	**0 (0%)**	**2 (10%)**	**4 (20%)**	**7 (35%)**
Hallucination	**0**	**0**	**0**	**0**	**0**	**0**