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Research Article

Association of induced intraoperative hypotension with acute kidney injury after functional endoscopic sinus surgery.

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Abstract

Background; although surgical field visualization is important in functional Endoscopic sinus surgery (FESS), the complications associated with controlled hypotension for surgery should be considered. Intraoperative hypotension (IOH) may be associated with postoperative acute kidney injury (AKI), but the duration of hypotension for triggering harm is unclear, **Aim and objectives;** early evaluation of acute kidney injury (AKI) following induced hypotension during FESS operation using kidney biomarker as NGAL, **Subjects and methods;** This prospective cohort study was conducted in anaesthsia and intensive care department in Minia University Hospital in the period from April 2021 To April 2022, after obtaining Institutional Ethical Committee approval and written informed consent from patients. A total number of twenty male & female patients aged 18-60 years with BMI 23-27 and ASA physical status I & II who were candidate for (functional endoscopic sinus surgery) FESS under the effect of hypotensive anaesthesia, were enrolled in this prospective cohort study, **Result** Demographic data of the studied population (n=20), including 11 males (55%) and 9 females (45%), and mean of age of 36.50 ±10. Regarding Comparison between urea and creatinine levels by Wilcoxon Signed Ranks Test, there were non-significant change between preoperative, 3 hours post-operative and 3 days post-operative levels. There was a significant difference between preoperative and 3 hour postoperative NGAL in the studied group **Conclusion;** NGAL is the most sensitive biomarker that can detect early acute kidney injury in patients who are going to do FESS operation that exposed to hypotensive anesthesia. Only 9% of patients who are going to do FESS operation had acute kidney injury. Hypotensive anesthesia technique should be within limits to decrease the incidence of AKI in patients who are going to do FESS operation, Aim of the study is to evaluate the effect of Hypotensive anesthesia during FESS. **Primary outcome**; detection of NGAL as a biomarker in predicting AK. **Secondary outcome**; detection of the effect of hypotensive anesthesia on hemodynamics and other vital organs.

Keyword; FESS; Acute kidney injury; Intraoperative hypotension.

Introduction

Functional endoscopic naso-sinusal surgery (FESS) targets sinus pathology and is the gold standard for treating chronic rhinosinusitis (CRS). Also, it can be used for treatment of other pathologies as sinus tumors, cerebrospinal fluid leak and lesions of the petrous apex [(1).]

Hypotensive anesthesia (HA) has been used for decades to decrease intraoperative blood loss and thus reduce the need for an allogeneic blood transfusion [(2)].

But the use of hypotensive anesthesia in FESS has many disadvantages as on the vital organs one of them is acute kidney injury (AKI); in the

past AKI diagnosis depend on elevation of serum creatinine but now the availability of biomarkers like neutrophil gelatinase–associated lipocalin (NGAL),*w*hich *released* from kidney tubular cell under stress as well as from neutrophils during inflammation determination of NGAL has been suggested the most important biomarker. [3].

Hypotensive anesthesia can be done by either; pharmacological methods like: Sodium nitroprusside (SNP) and nitroglycerin (NTG), they are two of very potent hypotensive agents that are commonly used for inducing hypotensive anesthesia , Trimethaphan, Calcium channel antagonists (e.g., nicardipine), , β-adrenoceptor antagonists (e.g., propranolol and esmolol) which have been effectively used for inducing hypotensive anesthesia for maxillofacial operations when administered either as a single hypotensive agent or in combination with SNP [4], [5], or non-pharmacological methods like: *1. The Anti-Ttrendelenburg Position.* Hypotension in the anesthetized patient can be easily achieved by placing the patient in a head-up or anti-Trendelenburg position because of orthostatic or postural hypotension results, *2. Acute Normovolemic Hemodilution (ANH)* (ANH is accomplished by drawing a unit or two of the patient's blood either immediately before or shortly after the induction of anesthesia and simultaneously replacing it with a cell-free fluid, preferably a synthetic colloid solution) [6].

Patients and Methods

Ethical approval , faculty of medicine minia university research ethical committee(FMREC) gave the clearance of the research and all procedures were carried out in compliance with its relevant polcies and procedures at approval number(7.2021)

This prospective cohort study was conducted in otolaryngology department in Minia University Hospital in the period from April 2021 To April 2022, after obtaining Institutional Ethical Committee approval and written informed consent from patients.

A total number of twenty male &female patients aged 18_60 years with body mass index (BMI 23_270) and ASA physical status I & II, who was candidate for (functional endoscopic sinus surgery (FESS) under the effect of hypotensive anaesthesia, were enrolled in this prospective cohort study.

Patients with chronic medical diseases, mean arterial pressure (MAP) less than 65mm Hg, patients with history of allergy to any medical agents used in the study ,patients on regular renal dialysis, Pregnant females and Patients who refuse to participate in the study were excluded.

Anesthesia Regimen:

All patients were kept nil per oral the night before surgery. Standard monitors including pulse oximeter, noninvasive blood pressure, 5 lead electrocardiogram (ECG), end tidal CO_2 (EtCO2) and temperature probes were attached and baseline values recorded (Philips monitors, Germany).

All patients received 10 to 15 mL/kg normal saline fluid infusion. Patients were first pre-medicated with an infusion of midazolam 0.05 mg/kg, fentanyl 1 μg/kg and lidocaine 1 mg/kg. All the patients were pre-oxygenated with 100% oxygen for 3 minutes. Induction of anesthesia was achieved with an infusion of propofol 2 mg/kg, atracurium 0.5 mg/kg and after 3 to 5 minutes, patients were intubated with the appropriate tube size. Anesthesia was maintained with isoflurane 1.5%, atracurium with incremental dose 0.15 mg/kg every 30 minutes and 50 μg of fentanyl per hour. Ventilation was maintained to end-expiratory CO_2 tension at 35 ± 2 mm Hg (Drager medical AG/COKGaA; model 23542, Germany).

The hemodynamic endpoint of anesthetic management was the maintenance of mean blood pressure (MBP) at 60-70 mmHg for producing bloodless surgical field. To eliminate observer bias, the operating surgeon and the anesthetist were blinded to whether the patient had been given a beta blocker. Patients were placed in a 10°reverse trendlenburg position to improve venous drainage. Patients in both groups received topical application of mixture of 4 ml lignocaine 2% and 1 ml of epinephrine 1 in 1,000 on a well wrung out cotton pledges to the nasal mucous membrane, which was kept in situ for 10–15 min.

After removal of pledges, lateral nasal wall was infiltrated with 0.5–1 ml of 1% lignocaine with epinephrine 1 in 100,000–200,000 dilution before commencement of surgery.

At the end of surgery, administration of anaesthetic agent was discontinued and reversal of neuromuscular blockage was done using Inj. atropine sulfate in a dose of 0.02 mg/kg. IV injection plus+Inj. neostigmine (0.05mg/kg) IV injection. Endotracheal extubation was done after the return of adequate muscle tone, power, protective reflex (cough) and when the breathing pattern of patient was smooth. Patients were observed every 15 minutes till for 2two hours for Spo2, pulse rate, blood pressure, sedation score, visual analogue scale (pain), nausea and vomiting, complications and adverse effects; if any; were recorded

Measured parameters:

Primary*:*

- **NGAL**, measured preoperative and 3 hours postoperative

❖ **Assay principle for NGAL**

- This kit is an Enzyme-Linked Immunosorbent Assay (ELISA). The plate has been pre-coated with Human LCN2 antibody. LCN2 present in the sample is added and binds to antibodies coated on the wells. And then biotinylated Human LCN2 Antibody is added and binds to LCN2 in the sample. Then Streptavidin-HRP is added and binds to the Biotinylated LCN2 antibody. After incubation unbound Streptavidin-HRP is washed away during a washing step. Substrate solution is then added and color develops in proportion to the amount of Human LCN2.
- Detection of any complications on vital organs post operatively**.**

Secondary:

(1) Hemodynamics (Heart rate and mean arterial pressures were recorded immediately prior to induction of anesthesia and subsequently every 3 min for 15 min and then every 15 min till the termination of anaesthesia);

(2) Serum urea and creatinine. Total blood loss during surgery was calculated from the fluid volume of the suction canister. The volume of irrigating fluid was subtracted from the total volume of fluid collected in the suction bottle. A fully soaked cotton strip was estimated to contain 5 ml of blood and partially soaked one to contain 2-3 ml of blood;

(3) Surgical time was recorded from the first injection of regional anesthetic to the end of surgery;

(4) Number of patients receiving nitroglycerine infusion.

(5) Side effects: like hypotension, bradycardia, nausea and vomiting.

Statistical Analysis:

- Analyses will be done using SPSS program.
- Data will be presented as mean ± SD or median ± IQR or number and percentage.
- Analyses will be done for parametric quantitative data between the two groups using independent sample student test and for non- parametric quantitative data using Mann Whitney test.
- Analyses will be done for qualitative data between the two groups using Fisher's Exact test.

Sample size calculation:

Before the study, the number of patients required was determined after a power calculation according to data obtained previous study. In that study the proportion of (AKI was about **3.76**%. A sample size of **20** patients in each group was determined to provide **80**% power and **5**% type I error using the following equation: -

$$\textbf{Sample size} = \frac{Z_{1-\alpha}{}^{2} * P * (1 - P)}{d^{2}}$$

Z1-α/2=Is standard normal variate (at 5% type1 error (P<0.05) it is 1.96

p=Expected proportion in population based on previous studies.

d=Absolute error or precision–Has to be decided by researcher (8.5).

Three patients will be added to each group to compensate for drop out of patients so, the total numb

Results

After completing the study on a total of 20 patients, the key was opened showing that clinical examination and clinical investigation of studied population had a role to detect acute kidney injury with hypotensive anesthesia.

- **Patients' characteristics**

Table (1) shows demographic data of the studied population (n=20), including 11 males (55%) and 9 females (45%), mean of age of 36.50 ±10, BMI of 25.45± 1.55 and duration of operation of 105.14±14.86

Table (1): Demography of the studied population.

Characteristic	Cases (n =20)
Age (years) **Mean ± SD**	36.50 ± 10.00
Gender **Male** **Female**	11(55.0%) 9 (45.0%)
BMI **Mean ± SD**	25.45± 1.55
Duration of operation (minute) **Mean ± SD**	105.14±14.86

Data displayed as mean, standard deviation (SD), number and percent.

- **Changes in the level of Neutrophil Gelatinase-associated Lipocalin (NGAL)(ng/ml) in study group:**

As illustrated in table (2) and figure (1), the assessment of serum NGAL showed that there was a significant difference between preoperative and 3 hour postoperative NGAL in the studied group.

Table (2): NGAL test among the studied population pre-operative and post-operative.

Characteristic	Pre-operative	3 hour post-operative	p-value
NGAL **Median±interquartile range**	132.50±27.75	161.50±19.25	<0.0001*

- ***Data displayed as Median ± interquartile range***
- ***Significant level at P value < 0.05***

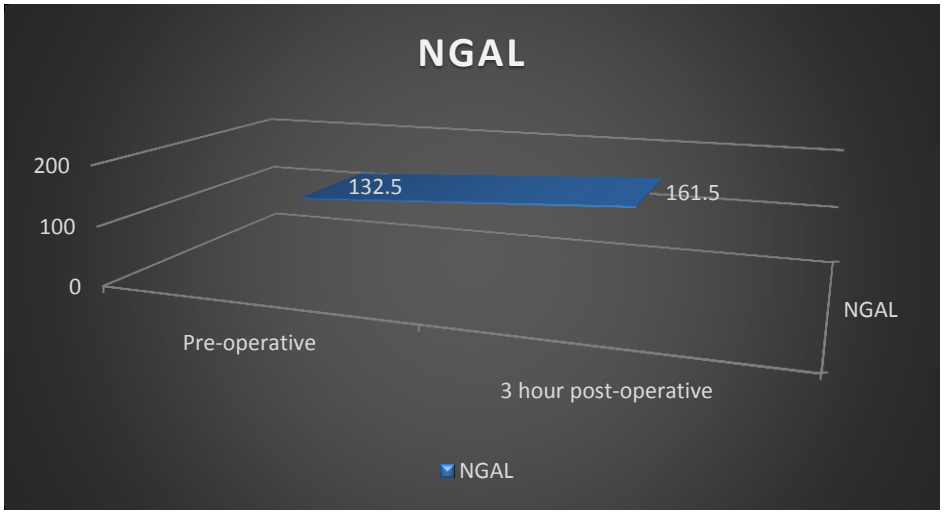

Figure (1): NGAL test among the studied population.

- **Changes in urea and creatinine levels.**

Comparison between urea and creatinine levels by Wilcoxon Signed Ranks Test during the pre and postoperative periods showed that the changes between preoperative, 3 hours post-operative and 3 days post-operative levels were non-significant.

Table (3): Urea and creatinine levels during the pre-operative and post-operative periods.(n=20)

Characteristic	Pre-operative (A)	3 hours post-operative (B)	3 days post-operative©	p- value		
				(A)Vs(B)	(A)Vs(C)	(b)Vs(C)
creatinine mg/dl Median±interquartile range	0.70 ± 0.20	0.70 ± 0.18	0.70 ± 0.20	0.876	0.117	0.312
urea mg/dl Median±interquartile range	27.00 ± 8.75	27.00 ± 6.50	30.00 ± 8.75	0.399	0.561	0.116

- ***Data displayed as Median ± interquartile range***
- ***Significant level at P value < 0.05***

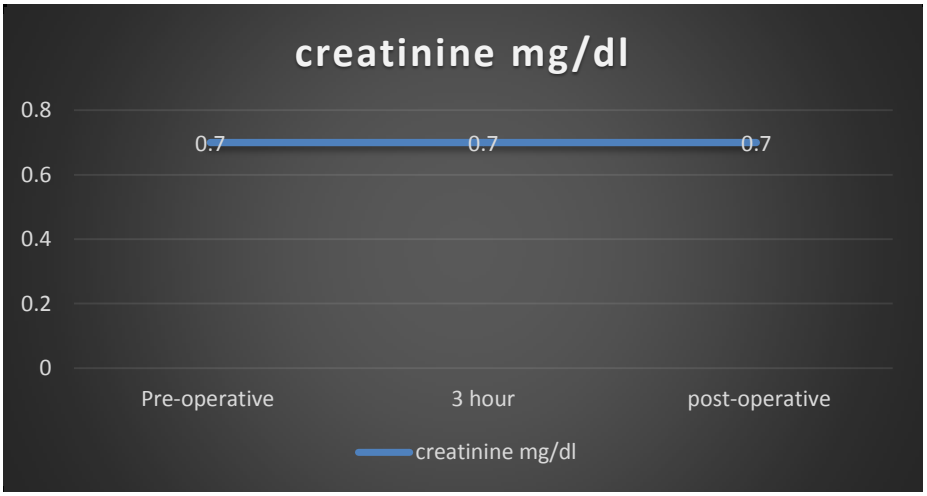

Figure (2): Creatinine of the studied population.

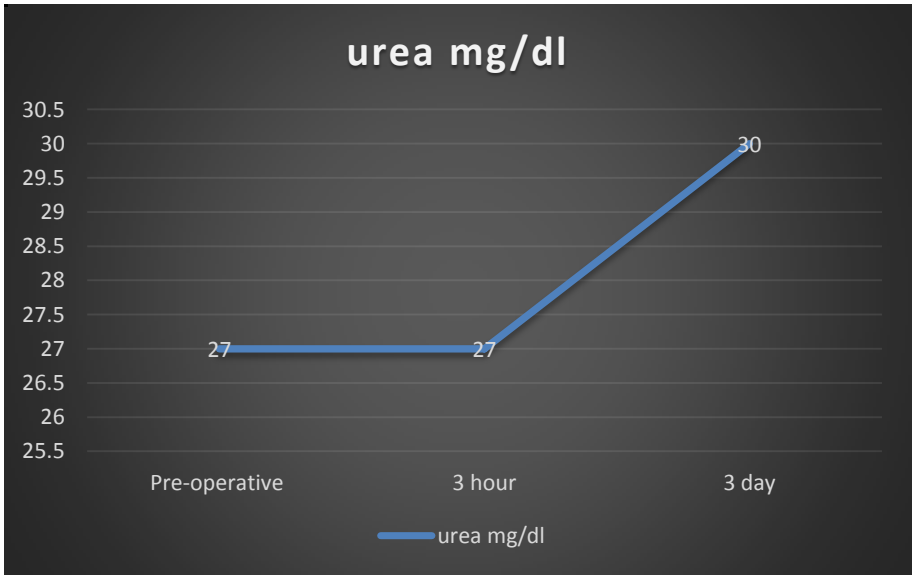

Figure (3): Urea of the studied population.

Changes in the oxygen saturation:
No significant difference in the pre-operative, intra operative and post-operative oxygen saturation of the studied population. **Changes in the respiratory rate:**
Table 2 summarizes the changes in the respiratory rate of the studied population with no significant differences between pre-operative, intra operative and post-operative periods.

Table (4): Respiratory rate of the studied population (n=20)

Characteristic	Pre-operative (A)	intra operative (B)	post-operative (C)	p- value		
				(A)Vs(B)	(A)Vs(c)	(B)Vs(C)
Respiratory rate (cycle/min) Mean ± SD	18.25 ±1.86	18.90 ± 1.80	18.00 ± 1.49	0.263	0.644	0.064

- ***Data displayed as mean, standard deviation (SD).***

Changes in the urine output:
As shown in table 3, there was significant difference between pre-operative and post-operative urine output.

Table (5): Urine output among the studied population pre-operative and post-operative **(n=20)**

Characteristic	Pre-operative	post-operative	p- value
UOP(ml/hr) Mean±SD	78.58 ± 22.64	59.91 ± 18.88	0.003*

- ***Data displayed as mean, standard deviation (SD)***
- ***Significant level at P value < 0.05***

Table (6): Changes in the oxygen saturation of the studied population pre-operative, intra operative and post-operative.

Pre-operative pao2 (Mean ± SD 98.65 ± 1.39)		
Vs	**Mean ± SD**	**p-value**
5 min(PIA)	98.35 ± 1.18	0.554
10 min(PIA)	98.60 ± 1.09	0.909
15 min(PIA)	98.50 ± 1.28	0.679
30 min(PIA)	98.60 ± 1.88	0.915
60 min(PIA)	98.70 ± 1.26	0.847
post-operative	98.50 ± 1.05	0.679

- **(pao2) oxygen saturation**
- ***(PIA) post-induction of anesthesia***

- **Hemodynamic changes:**

Changes in the heart rate (beat/min):
As regard heart rate, there was a significant difference between preoperative heart rate and the heart rate throughout the intraoperative and post-operative periods.

Table (7): Changes in the heart rate of the studied population pre-operative, intra operative and post-operative

Pre-operative Heart rate (Mean ± SD 78.60 ± 6.12)		
Vs	**Mean ± SD**	**p-value**
1 min(PIA)	74.20 ±4.73	0.034*
5 min(PIA)	73.10 ± 5.79	0.016*
10 min(PIA)	74.70 ± 5.45	0.073
15 min(PIA)	75.05 ± 4.99	0.074
20 min(PIA)	73.00 ±5.04	0.006*
30 min(PIA)	73.25 ± 5.34	0.013*
45 min(PIA)	72.80 ± 5.18	0.006*
60 min(PIA)	73.65 ± 4.63	0.030*
Post-operative	98.25 ± 6.84	<0.0001*

- ***(PIA) post-induction of anesthesia***
- ***Data displayed as mean, standard deviation (SD)***
- ***#: significant difference within the group in comparing with the base line (p value ≤ 0.05).***

Changes in the mean arterial blood pressure (MAP) (mmHg):

Table 8 shows the summary of changes in the mean arterial pressure (mmHg) with a significant difference between preoperative and intraoperative MAP.

Table (8): Changes in the mean arterial pressure (mmHg) of the studied population in the pre-operative, intra operative and post-operative period.

Pre-operative MAP (Mean ± SD 89.25 ± 4.756)		
Vs	**Mean**	**p- value**
1 min (PIA)	72.05 ± 4.21	<0.0001*
5 min (PIA)	72.55 ± 3.38	<0.0001*
10 min(PIA)	72.15 ± 3.67	<0.0001*
15 min(PIA)	72.60 ± 3.36	<0.0001*
20 min(PIA)	71.60 ± 3.33	<0.0001*
30 min(PIA)	71.65 ± 3.27	<0.0001*
45 min(PIA)	71.60 ± 4.07	<0.0001*
60 min(PIA)	72.05 ± 2.96	<0.0001*
Post-operative	88.05 ± 5.68	<0.0001*

- ***(PIA) post-induction of anesthesia***
- ***(MAP) mean arterial pressure***
- ***Data displayed as mean, standard deviation (SD)***

Table (9): Correlation between post-operative NGAL and the mean arterial pressure (mmHg) post-induction of anesthesia

MAP	Post -operative NGAL (Vs)	
1 min(PIA)	R	p- value
	-0.672	0.001*
5 min(PIA)	R	p- value
	-0.445	0.049*
10 min(PIA)	R	p- value
	-0.572	0.008*
15 min(PIA)	R	p- value
	0.582	0.007*
20 min(PIA)	R	p- value
	-0.367	0.111
30 min(PIA)	R	p- value
	-0.507	0.022*
45 min(PIA)	R	p- value
	-0.489	0.029*
60 min(PIA)	R	p- value
	-0.729	<0.0001*

- ***PIA) post-induction of anesthesia***
- ***(MAP) mean arterial pressure***
- ***Significant level at P value < 0.005***

Discussion

Our result revealed that NGAL was elevated in 3 cases while BUN an S. CR elevated in 2 cases. This means that NGAL is sensitive but not specific for AKI and this was supported by Faggioni et al., 2001[7], who supposed that NGAL is also increased in other conditions besides ischemic AKI as in patients with autosomal dominant polycystic kidney disease.

When a correlation was done between post-operative NGAL and the mean arterial pressure (mmHg) post-induction of anesthesia, it was found that there was a significant negative correlation between them. This means that the lower the mean BP, the higher the risk of AKI. This finding is important as individualized anaesthetic management to minimize hypotension if possible.

In contrast, detection of NGAL has been shown to be a more effective, sensitive and highly predictive early biomarkers of AKI. This is in agree with a study made by Dent et al., 2007[8] in which, plasma and urinary NGAL rose significantly at 2 hours after CPB.

Despite direct causality between AKI and death has been a controversial, AKI associates with high morbidity and mortality. About 1.7 million deaths per year (Mehta et al., 2015),[9].

According to KDIGO 2012 (Kidney Disease: Improving Global Outcomes), Acute Kidney Injury Network (AKIN) criteria depend on increase in serum creatinine and blood urea nitrogen (BUN) with diminished UOP.

There is no uniform definition for intra operative hypotension (IOH). A systematic review identified over 140 different definitions for IOH in 130 studies; definitions were based on systolic AP (SAP) or mean AP (MAP) values, absolute values or relative and changes or a combination of them.

IOH has important role in reducing bleeding that occur intra operative thus simplify surgical procedures (Cardesı´n et al., 2013)[10]. Also, it can be associated with major postoperative complications including myocardial injury (Sessler et al., 2018),[11], acute kidney injury (Salmasi et al., 2017),[12] and death (Stapelfeldt et al., 2017),[13].

NGAL, Neutrophil gelatinase–associated lipocalin (NGAL) is a protein of the lipocalin family. The rapidly evolving knowledge about NGAL kinetics in AKI suggest that NGAL gene up regulation occurs in two major areas in early phase of AKI, namely, kidney and other systemic organs like lungs and liver (KM et al., 2007)[14].

NGAL was selected, because it has been found as a promising biomarker for early diagnosis, predicting disease severity, therapeutic monitoring, and predicting clinical outcomes of AKI (Ronco, 2008)[15].

In our study, the aim was to determine whether induced intraoperative hypotension can lead to AKI during FESS operation.

Regarding to serum urea and creatinine, they doesn't increased during the early 3 hours post-operative, but the increase occurred 3 days later in two patients with no significant difference from preoperative measurement. This means that, serum creatinine and blood urea are not sensitive to the loss of kidney reserve. These findings are supported by KDIGO Clinical Practice Guideline for Acute Kidney Injury, 2012, which suggested that the use of both the blood creatinine and the urine output is more accurate than the measurement of creatinine alone because the change in creatinine is delayed after injury to the kidney and depends on both the endogenous production and the decline in excretion of creatinine.

With respect to UOP, it's decreased postoperative in some patients specially the two patients with increased serum urea and creatinine, supporting the diagnosis of AKI according to KDIGO criteria. (Petäjä et al., 2017)[16], suggested that both elevated S.Cr levels and postoperative oliguria may increase morbidity and mortality. This is in agree with Stuart et al., 2020,[17]who support the concept that assessment and recognition of oliguria, and its effect on patient fluid accumulation and serum creatinine based AKI diagnosis ascertainment, are crucial for management of critically ill patients at risk for AKI.

On the other side, most recent AKI studies focusing on orthopedic patients have ignored the UOP criteria altogether and focused solely on S.Cr as Porter et al., 2017,[18]. In addition a study of hepatectomy and AKI concluded that postoperative UOP correlated poorly with sCr (Joliat et al., 2020),[19].

Limitations of the study

In our study, we faced some limitations as:

Small number of patients and the follow up of the patients was limited to the hospital period.

Conclusion

In conclusion, NGAL is the most sensitive biomarker that can detect early acute kidney injury in patients who are going to do FESS operation that exposed to hypotensive anesthesia.

Only 9% of patients who are going to do FESS operation had acute kidney injury. Hypotensive anesthesia technique should be within limits to decrease the incidence of AKI in patients who are going to do FESS operation.

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