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Development and Validation of A Stability-Indicating LC-Method for the Simultaneous Determination of Levocetirizine and Pseudoephedrine in Liquid Preparations

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Abstract
A stability-indicating ion-pairing reversed-phase high performance liquid chromatographic method has been developed for the simultaneous determination of Levocetirizine Dihydrochloride and Pseudoephedrine Sulfate and for the simultaneous determination of Levocetirizine Dihydrochloride and Pseudoephedrine Hydrochloride in an oral liquid formulation. The mobile phase consisted of a mixture of methanol, acetonitrile, and phosphate buffer solution 0.05M (pH=3.0) (45:15:30)(v/v/v) containing 2.5 g of triethylamine hydrochloride (Tailing-reducer Reagent) and 1.75 g of sodium dodecyl sulfate (Ion-pairing Reagent) per 1000 mL of solution at a flow rate of 1 mL/min. The column temperature was an ambient temperature. Detection wavelength was 242 nm using a photodiode array detector. The column was C18, 4.6-mm × 250-mm (5 μm). The method was validated according to ICH guidelines and the validation study showed accepted results for specificity, linearity, accuracy and precision. The linear range was 10 to 200 μg/ml for Levocetirizine Dihydrochloride, 240 to 4800 μg/ml for pseudoephedrine sulfate and 120 to 2400 μg/ml for pseudoephedrine hydrochloride. The correlation coefficients for Levocetirizine dihydrochloride, Pseudoephedrine sulfate and Pseudoephedrine hydrochloride were 0.9998, 0.9997 and 0.9999 respectively. The proposed method can be successfully used for quality control and stability studies of Levocetirizine and Pseudoephedrine in combination in oral liquid dosage forms.

Keywords: Levocetirizine dihydrochloride; Pseudoephedrine sulfate; Pseudoephedrine hydrochloride; IP-RP-HPLC; Method Validation; Stability-indicating LC-Method.

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Accepted 17/11/2014
1- Introduction:

Levocetirizine, one of the two active ingredients of the oral solution, is the R-enantiomer of cetirizine, and is used similarly, as the hydrochloride, for the symptomatic relief of allergic conditions including rhinitis and chronic urticaria [1]. It is an antihistamine; its principal effects are mediated via selective inhibition of $H_1$ receptors [2]. Levocetirizine dihydrochloride is mentioned in IP [3] and Eur.Ph[4].

Pseudoephedrine, the other active ingredient of the oral solution, is an alkaloid obtained from Ephedra spp, it is a stereoisomer of ephedrine and has a similar action. It is a direct- and indirect-acting sympathomimetic [1]. Pseudoephedrine is a decongestant that works by narrowing the blood vessels in the nose to decrease swelling and congestion. Pseudoephedrine and its salts are given orally for the symptomatic relief of nasal congestion [1]. Two synthetic salts of Pseudoephedrine were studied in this study: Pseudoephedrine Sulfate and Pseudoephedrine hydrochloride. Pseudoephedrine sulfate and Pseudoephedrine hydrochloride are benzenemethanol compounds and are mentioned in USP [5]. The chemical structures of Levocetirizine dihydrochloride, Pseudoephedrine sulfate and Pseudoephedrine hydrochloride used in this study, are shown in Fig (1).

![Chemical structures of Levocetirizine Dihydrochloride, Pseudoephedrine Sulfate and Pseudoephedrine Hydrochloride](image)

The purpose of this study was to develop a new stability-indicating liquid chromatographic analytical method for the
simultaneous determination of Levocetirizine dihydrochloride and Pseudoephedrine sulfate as well as for the simultaneous determination of Levocetirizine dihydrochloride and Pseudoephedrine hydrochloride in their oral solution formulations using the ion-pairing technology and to validate the developed analytical method.

A major challenge in developing a stability-indicating method (SIM) is the access to suitable degraded samples to aid in method development. Forced degradation studies involve the exposure of representative samples of drug product to the relevant stress conditions of light, heat, and oxidation. The results of forced degradation studies can facilitate SIM development, drug formulation design, selection of storage conditions and packaging type, better understanding of potential liabilities of the drug molecule chemistry, and solving of stability-related problems [6].

A stability indicating ion-pairing reverse-phase high performance liquid chromatographic method was reported for the simultaneous determination of Levocetirizine Dihydrochloride and Pseudoephedrine Sulfate in tablet dosage forms by using gradient elution. The mobile phase A consisted of Potassium dihydrogen phosphate Buffer 0.05M and 1-Ocatne sulphonol acid sodium salt 0.25%, pH adjusted to 3.0 with orthophosphoric acid. The mobile phase B was Acetonitrile [7].

2- Experimental:
Chemicals and Reagents:

Levocetirizine Dihydrochloride was obtained from Auctus phama Limited Unit-11, India. Pseudoephedrine Sulfate and Pseudoephedrine Hydrochloride were obtained from Taj Pharmaceuticals Limited, India. Orthophosphoric acid was obtained from Prolabo, Rhone-Poulenc Ltd, EEC. Monobasic potassium phosphate, triethylamine hydrochloride, Methanol (HPLC-grade) and Acetonitrile (HPLC-grade) were obtained from Sigma Aldrich, Germany. Sodium dodecyl sulfate was purchased from Merck, Germany. Water (HPLC-grade) was obtained from water purification system in the Faculty of Pharmacy, University of Aleppo, Syria. Hydrogen peroxide (H₂O₂) was obtained from Merck, India. The 0.45-um nylon membrane filter was obtained from Cromtech, India. The combination product of Levocetirizine dihydrochloride 0.5 mg/mL and Pseudoephedrine sulfate 12 mg/mL Developed Oral Solution and the combination product of Levocetirizine dihydrochloride 0.5 mg/mL and Pseudoephedrine hydrochloride 6 mg/mL Developed Oral Solution
were formulated in the Faculty of Pharmacy, University of Aleppo, Syria [8]. Double distilled water was used throughout the experiment for preparing the standard and sample solutions.

**Instruments:**

A liquid chromatograph (Shimadzu LC-20 AT, Japan) with a photodiode array detector and a reversed phase C18, 4.6-mm × 250-mm Agilent column that contains packing (5 μm) was used to perform analytical work.

UV–visible spectrophotometer (JASCO V-650, Japan) was used to record UV spectrums of solutions. A titromatic pH-meter (Crison, Spain) was used to test pH of solutions. An ultrasonic bath (Grant Instruments (Cambridge) Ltd,) was used to degas the mobile phases.

A lamp of UV light (λ = 365 nm) was also used in the study to provide exposure to light.

**Methods:**

**Method development:**

To investigate the appropriate wavelength for simultaneous determination of Levocetirizine and Pseudoephedrine, single solutions of Levocetirizine Dihydrochloride, Pseudoephedrine Sulfate and Pseudoephedrine Hydrochloride in water having the same concentrations of these compounds and the same methanol content in the sample preparation were scanned by UV–visible spectrophotometer in the wavelength range 200–400 nm. For the first combination (Levocetirizine Dihydrochloride and Pseudoephedrine Sulfate), the detection wavelength was inferred from the recorded overlain spectra of Levocetirizine Dihydrochloride and Pseudoephedrine Sulfate. Similarly, for the second combination (Levocetirizine Dihydrochloride and Pseudoephedrine Hydrochloride), the detection wavelength was inferred from and from the recorded overlain spectra of Levocetirizine Dihydrochloride and Pseudoephedrine Hydrochloride. For the two combinations, the overlain UV spectra showed that the detection wavelength (isobestic wavelength) was 242 nm as shown in Fig (2). So, Sample preparation of each analyte of each combination was prepared and injected directly for HPLC analysis and the peak areas were recorded at the isobestic wavelength: 242 nm.

Since Pseudoephedrine is a basic analyte, ion-pairing reagents (sodium dodecyl sulfate and 1-heptanesulfonic acid sodium salt) were used to provide an additional parameter to facilitate separation of pseudoephedrine sulfate (or hydrochloride) from Levocetirizine
Dihydrochloride in the sample. As USP uses Triethylamine Hydrochloride as one of the components of mobile phase of Assay in many monographs containing Pseudoephedrine, similarly, Triethylamine Hydrochloride was added as amine modifier in the mobile phase of the developed analytical method to reduce peak tailing caused by the strong interaction of basic Pseudoephedrine with acidic surface silanol groups contained in silica packing of the stationary phase [5, 9].

The mobile phase was optimized after trials using several mobile phase compositions with various volumetric proportions of phosphate buffer, methanol and acetonitrile (organic solvents) and at various types and concentrations of ion-pairing reagents.

Chromatographic Conditions:

The chromatographic system used was a Shimadzu LC-20 AT liquid chromatograph comprised of degasser, quaternary pump, auto sampler, column compartment, photodiode array detector and the system was controlled through Empower Software equipped with a photodiode array detector).

Preparation of Mobile Phase:

Phosphate Buffer Solution 0.05 M (pH=3.0): Dissolve 3.4 g of monobasic potassium phosphate in 450 ml of water, add 1.0 mL of phosphoric acid and dilute with water to 500 mL.

Organic Solvents: Methanol, Acetonitrile.

Prepare a mixture of methanol, acetonitrile, and buffer solution (45:15:30) containing 2.5 g of triethylamine hydrochloride, 1.75 g of sodium dodecyl sulfate per 1000 mL of solution, filter and degas.

Flow Rate of Mobile Phase: 1 mL per minute. Detector Wavelength: 242-nm (the detector wavelength was kept at 242 nm using a photodiode array detector). Column Temperature: The column temperature was kept at ambient temperature. Injection volume: 20 µL. Run time: 20 min.

Effect of pH:

pH of mobile Phase is one of the important factors affecting the separation and the retention times of the analytes in the ion-pairing chromatography. The experiments showed that the lower values of pH gives is better for the positions and retention times of the Levocetirizine and Pseudoephedrine peaks. The optimum value of pH is pH=3.0.

Standard Solution Preparation:
A 50 mg of Levocetirizine Dihydrochloride Standard was accurately weighed, and transferred to a 100-mL volumetric flask and dissolved in water, then diluted with water to the required volume then well-agitated (Levocetirizine Dihydrochloride Standard Stock Solution).

A 120 mg of Pseudoephedrine Sulfate Standard (or 60 mg Pseudoephedrine Hydrochloride Standard) was accurately weighed, and transferred to a 50-mL volumetric flask and dissolved in water. To the same flask, 10 mL of Levocetirizine Dihydrochloride Standard Stock Solution and 10 ml of methanol were added and diluted with water to the required volume and mixed for 5 minutes by using a magnetic stirrer and filtered through a 0.45-μm membrane filter.

**Sample Preparation:**

10 ml accurately measured of the developed and prepared oral solution [8] and 10 ml of methanol were transferred to a 50-mL volumetric flask, and the resulting solution was diluted with water to the required volume and mixed for 5 minutes by using a magnetic stirrer and filtered through a 0.45-μm membrane filter.

**Forced Degradation Studies of Drug Product:**

The stability indicating power and the specificity of the proposed analytical method were demonstrated by forced degradation studies. The following three solutions: Levocetirizine dihydrochloride and pseudoephedrine sulfate oral solution, Levocetirizine Dihydrochloride and Pseudoephedrine Hydrochloride oral solution and placebo solution, were exposed to three types of degradation: oxidative degradation, thermal degradation and photo-degradation. The hydrolysis degradation (Acid, Base, and Thermal) was not performed as the developed oral solutions and placebo were buffered formulations [6].

**Oxidative Degradation:**

10 ml of each of the following solutions: Levocetirizine dihydrochloride and Pseudoephedrine sulfate oral solution, Levocetirizine dihydrochloride and pseudoephedrine hydrochloride oral solution and placebo solution, was accurately measured and transferred to a 50-ml volumetric flask, 10.0 ml of 3.0 % Hydrogen peroxide solution was added and the resulting solution was kept for two days at room temperature, protected from light, then 10 ml of methanol was added and the resulting solution was diluted with water
to volume (50-ml) and mixed for 10 min with intermittent shaking, and filtered through a 0.45-μm membrane filter.

Photo-degradation:

10 ml of each of the following solutions: levocetirizine dihydrochloride and pseudoephedrine sulfate oral solution, levocetirizine dihydrochloride and pseudoephedrine hydrochloride oral solution and placebo solution, was accurately measured and transferred to a 50-mL beaker and kept for two days under lamp of UV light (λ = 365 nm), then 20 ml of water was added and the resulting solution was transferred to a 50-ml volumetric flask, then 10 ml of methanol was added and the resulting solution was diluted with water to volume (50-ml) and mixed for 10 min with an electromagnetic stirrer, and filtered through a 0.45-μm membrane filter.

Thermal Degradation:

10 ml of each of the following solutions: levocetirizine dihydrochloride and pseudoephedrine sulfate oral solution, levocetirizine dihydrochloride and pseudoephedrine hydrochloride oral solution and placebo solution, was accurately measured and transferred to a 50-ml volumetric flask closed with aluminium foil and kept for two days in an oven at 70°C, then 10 ml of methanol was added and the resulting solution was diluted with water to volume (50-ml) and mixed for 10 min with an electromagnetic stirrer, and filtered through a 0.45-μm membrane filter.

Method Validation:

The validation of the developed stability-indicating method was performed according to The International Conference on Harmonisation (ICH) guidelines [10].

Specificity:

Direct evaluation of specificity of the developed analytical method was performed in-line by employing photo-diode array (PDA) detection. Specificity was demonstrated by the resolution of the two components which elute closest to each other. The complete separation of Levocetirizine dihydrochloride and Pseudoephedrine sulfate (or Hydrochloride) was achieved in presence of the excipients of the oral solution. In addition there was no any interference at the retention time of Levocetirizine dihydrochloride and Pseudoephedrine sulfate (or hydrochloride) in the chromatogram of the sample preparation of the oral solution compared with the chromatogram of the sample preparation of placebo solution.
Forced degradation studies was performed on the drug product to provide an additional evidence of specificity. Specificity was demonstrated by comparing the test results of oral solution and placebo samples stored under stress conditions: light, heat and oxidation.

**Linearity:**

Linearity of the method was demonstrated on the drug substances (levocetirizine dihydrochloride, pseudoephedrine sulfate and pseudoephedrine hydrochloride). A standard stock solution of each drug substance was diluted to make 11 concentrations across a range of 10 to 200% of the targeted level of the assay concentration (Assay concentrations for Levocetirizine dihydrochloride, Pseudoephedrine Sulfate and Pseudoephedrine Hydrochloride was 100 μg/mL, 2400 μg/mL and 1200 μg/mL respectively). Sample preparations of the eleven concentrations were prepared, using the proposed procedure. These sample preparations were chromatographed and the peak responses were recorded as directed for analytical method procedure.

Linearity was evaluated by visual inspection of a plot of peak areas as a function of analyte concentration for each analyte. A linear relationship between the peak area and concentration for each analyte was evaluated across the range of the analytical procedure.

**Range:**

The specified range was derived from linearity studies and was suitable for the assay purpose.

**Accuracy:**

Accuracy was established across the specified range of the analytical procedure (10 to 200% of the test concentration). Solutions of the placebo were spiked with stock solutions containing known quantities of the corresponding two drug substances. Accuracy was determined by the application of the analytical procedure to the placebo to which known quantities of the drug substances to be analysed have been added. Accuracy was assessed using 9 total determinations over 3 concentration levels (10%, 100%, 200%) covering the specified range (3 replicates of each concentration each of the total analytical procedure).

**Precision:**

The precision of the developed analytical method was investigated. Repeatability was assessed using 6 determinations at 100% of the test concentration of each analyte. The days variation was studied to establish the intermediate precision.
3- Results and Discussion:

3-1- Optimization of the chromatographic conditions:

The chromatographic conditions was optimized to develop a stability indicating method for the simultaneous determination of levocetirizine and pseudoephedrine in the oral solution.

The overlain UV spectra of levocetirizine dihydrochloride and pseudoephedrine sulfate exhibited cross absorption of the two drugs at 242 nm which is the isobestic wavelength. Similarly the overlain UV spectra of Levocetirizine dihydrochloride and Pseudoephedrine hydrochloride exhibited cross absorption of the two drugs at 242 nm which is also the isobestic wavelength, so this wavelength was chosen as the detection wavelength for the analysis for the two combinations. It was observed that there was no interference from the mobile phase or baseline disturbance at 242 nm. It was, therefore, concluded that 242 nm is the most appropriate wavelength for analysis of the two analytes with suitable sensitivity. The recorded overlain UV spectra of Levocetirizine dihydrochloride and Pseudoephedrine sulfate and The recorded overlain UV spectra of Levocetirizine dihydrochloride and Pseudoephedrine hydrochloride are shown in Fig (2).

The chromatograms at 242 nm showed a complete resolution of all the peaks. The proportion and composition of the optimized mobile phase (consisting of a mixture of methanol, acetonitrile, and buffer solution 0.05 M (45:15:30) (v/v/v) containing 2.5 g of triethylamine hydrochloride and 1.75 g of sodium dodecyl sulfate per 1000 mL of solution) gave good resolution (the resolution was more than 2) and
acceptable peak parameters for both Levocetirizine and pseudoephedrine for the two combinations which resulted in sharp and symmetrical peaks for the two analytes. The addition of triethylamine hydrochloride to the composition of the mobile phase gave a peak for Levocetirizine with minimal tailing (the tailing factor was less than 2), so, by using this optimized mobile phase maximum separation and sensitivity and better peaks parameters were achieved. A flow rate of 1 mL per minute gave an optimal signal to noise ratio with a reasonable separation time. The observed retention times for levocetirizine dihydrochloride and pseudoephedrine sulfate were 14.9 min and 6.4 min respectively in the Levocetirizine dihydrochloride and Pseudoephedrine Sulfate Oral Solution and the observed retention times for levocetirizine dihydrochloride and pseudoephedrine hydrochloride were 14.9 min and 6.6 min respectively in the Levocetirizine Dihydrochloride and Pseudoephedrine Hydrochloride Oral Solution. The typical chromatograms for the two combinations are recorded as shown in Fig (3) and Fig (4).

The peak impurity was not detected. The resolution between pseudoephedrine and Levocetirizine was not less than 2.0 for the two
combinations. The tailing factor for the pseudoephedrine peak was not more than 2.5 for the two combinations. The relative standard deviation for replicate injections was not more than 2.0% for the two combinations. The results of impurity of peak, resolution between the analyte and the closer peak and tailing factor are included in Table (1).

Table (1). Results of peak impurity, resolution between the analyte and the closer peak, and tailing factor of Levocetirizine and Pseudoephedrine peaks

<table>
<thead>
<tr>
<th>Peak Parameter</th>
<th>Levocetirizine dihydrochloride &amp; Pseudoephedrine sulfate Oral Solution</th>
<th>Levocetirizine dihydrochloride &amp; Pseudoephedrine hydrochloride Oral Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peak Impurity</td>
<td>Levocet.2HCl Pseudo.sulphate</td>
<td>Levocet.2HCl Pseudo.HCl</td>
</tr>
<tr>
<td>Impurity</td>
<td>Not Detected</td>
<td>Not Detected</td>
</tr>
<tr>
<td>Resolution</td>
<td>22.0</td>
<td>23.1</td>
</tr>
<tr>
<td>Tailing Factor</td>
<td>1.119</td>
<td>1.118</td>
</tr>
</tbody>
</table>

3-2- Forced Degradation Studies:

The results of forced degradation studies facilitated stability-indicating method development. From the results of the peak impurity, resolution between the analyte and the closer peak, and tailing factor of Levocetirizine and Pseudoephedrine peaks after the forced degradation studies (oxidative degradation, thermal degradation and photodegradation), we can be concluded that the developed analytical method is stability-indicating. The impurity of peak was not detected. The resolution between Pseudoephedrine and Levocetirizine was not less than 2.0 for the two combinations. The tailing factor for the pseudoephedrine peak was not more than 2.5 for the two combinations. The relative standard deviation for replicate injections was not more than 2.0% for the two combinations. The results of impurity of peak, resolution between the analyte and the closer peak and tailing factor are shown in Table (2).

Table (2). Summary of forced degradation results

<table>
<thead>
<tr>
<th>Peak Parameter</th>
<th>Levocetirizine dihydrochloride &amp; Pseudoephedrine sulfate Oral Solution</th>
<th>Levocetirizine dihydrochloride &amp; Pseudoephedrine hydrochloride Oral Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Impurity</td>
<td>Not detected</td>
<td>Not detected</td>
</tr>
<tr>
<td>Resolution</td>
<td>2.1</td>
<td>2.5</td>
</tr>
<tr>
<td>Tailing Factor</td>
<td>1.982</td>
<td>1.696</td>
</tr>
<tr>
<td>Peak Parameter</td>
<td>Parameter</td>
<td>Levocetirizine dihydrochloride &amp; Pseudoephedrine sulfate Oral Solution</td>
</tr>
<tr>
<td>---------------</td>
<td>-----------</td>
<td>-------------------------------------------------</td>
</tr>
<tr>
<td>Impurity</td>
<td>Not detected</td>
<td>Not detected</td>
</tr>
<tr>
<td>Resolution</td>
<td>17.5</td>
<td>2.1</td>
</tr>
<tr>
<td></td>
<td>1.9</td>
<td>1.9</td>
</tr>
<tr>
<td>Tailing.F</td>
<td>1.115</td>
<td>1.989</td>
</tr>
</tbody>
</table>

### Thermal Degradation

<table>
<thead>
<tr>
<th>Peak Parameter</th>
<th>Parameter</th>
<th>Levocetirizine dihydrochloride &amp; Pseudoephedrine sulfate Oral Solution</th>
<th>Levocetirizine dihydrochloride &amp; Pseudoephedrine Hydrochloride Oral Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Impurity</td>
<td>Not detected</td>
<td>Not detected</td>
<td>Not detected</td>
</tr>
<tr>
<td>Resolution</td>
<td>12.2</td>
<td>2.1</td>
<td>12.3</td>
</tr>
<tr>
<td></td>
<td>2.0</td>
<td>2.0</td>
<td></td>
</tr>
<tr>
<td>Tailing.F</td>
<td>1.117</td>
<td>1.982</td>
<td>1.119</td>
</tr>
</tbody>
</table>

3-3- Method Validation:

As per ICH guidelines [10], the method validation parameters were checked for specificity, linearity, precision and accuracy.

**Specificity:**

The representative chromatograms were used to demonstrate specificity as shown in Fig (5).
Fig (5). Representative Chromatograms of product and placebo of:
A. Levocetirizine Dihydrochloride and Pseudoephedrine Sulfate Oral Solution.
B. Levocetirizine Dihydrochloride and Pseudoephedrine HCl Oral Solution.

There was no interference between the excipients peaks and the analytes peaks. Resolution between closely eluting peaks and analytes peaks was greater than 2.0.

The peak purity test of each of the two analytes (levocetirizine and pseudoephedrine) for the two types of combinations using photo diode array detection showed that the impurity was not detected (single point threshold was less than peak purity index), and the peaks of analytes were pure, so peak purity test with photo diode array was useful to show that the analytes chromatographic peaks are not attributable to more than one component, indicating the stability indicating capability of the method. The peak purity curves are shown in Fig (6).
Fig (6). Peak Purity Curves of Levocetirizine and Pseudoephedrine of:
A. Levocetirizine Dihydrochloride and Pseudoephedrine Sulfate Oral Solution.
B. Levocetirizine Dihydrochloride and Pseudoephedrine HCl Oral Solution.
(Top: Levocetirizine, Bottom: Pseudoephedrine)

**Linearity:**

The evaluation of the relationship between the peak area and concentration for each analyte across the range of the analytical procedure showed that there was a linear relationship and test results was evaluated by appropriate statistical methods and a regression line was calculated by the method of least squares. Data from the regression line itself (regression analysis) was performed and it provided mathematical estimates which showed a high degree of linearity.

The results of correlation coefficient, y-intercept, slope of the regression line, residual sum of squares, standard error and regression line equation for the analytes were included in Table (3).

**Table (3). Results of Linearity**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Levocetirizine dihydrochloride</th>
<th>Pseudoephedrine sulfate</th>
<th>Pseudoephedrine hydrochloride</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correlation Coefficient (R)</td>
<td>0.9998</td>
<td>0.9997</td>
<td>0.9999</td>
</tr>
<tr>
<td>y-intercept</td>
<td>6001.62</td>
<td>1836.64</td>
<td>6386.21</td>
</tr>
<tr>
<td>Slope</td>
<td>12107.92</td>
<td>398.60</td>
<td>420.37</td>
</tr>
<tr>
<td>Residual Sum of Squares</td>
<td>1900359353</td>
<td>2172284675</td>
<td>169799098</td>
</tr>
<tr>
<td>Standard Error</td>
<td>14531.04</td>
<td>15535.92</td>
<td>4343.57</td>
</tr>
<tr>
<td>Regression Line Equation</td>
<td>y = 12107.92x +6001.62</td>
<td>y = 398.60x +1836.64</td>
<td>y = 420.37 x +6386.21</td>
</tr>
</tbody>
</table>
In addition, an analysis of the deviation of the actual data points from the regression line was also performed for evaluating linearity and was complying as shown in Fig (7) which represents plots of the data (a plot of responses (peak areas) as a function of analyte concentration) for each analyte with the corresponding regression analysis.

The confidence interval of the y-intercept of each analyte included zero.
Fig (7). Results and Plots of the Linearity Data
Range:
The chosen range was suitable for the assay purpose. A range from 10 to 200% of the test concentration was established as the analytical procedure provides an acceptable degree of linearity, accuracy and precision when applied to samples containing amounts of analytes within or at the extremes of this specified range of the analytical procedure. The specified range (10 to 200%) covered the ICH minimum specified range for the assay of finished (drug) product which is normally from 80 to 120% of the test concentration.

Accuracy:
Accuracy was reported as percent recovery by the calculation of the assay result of the known amount of each analyte spiked into the sample and the comparison to pre-set acceptance criteria derived from reference, and as the difference between the mean and the accepted true value together with the confidence intervals. The individual percent recoveries of each analyte were within the specified limits. The mean percent recoveries at each concentration level for each analyte and the overall mean percent recovery for each analyte were between 98 and 102%, indicating that the developed analytical method is accurate. The percent relative standard deviations for all analytes were less than 2.0%. The confidence intervals of the mean percent recovery for each analyte included the 100% value and the confidence intervals of the percent recoveries at each concentration level for each analyte were between 96 and 104%. All the results of the accuracy parameters showed the high accuracy of the developed analytical method. The results of accuracy parameters were reported in details in Table (4).

Table (4). Results of Accuracy

| Sample No. | Acceptance Criteria | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2HCl | Levocet.2Hcl
Precision:

The standard deviation, relative standard deviation (coefficient of variation) and confidence interval for each analyte were reported for the two types of precision investigated (Repeatability and Intermediate Precision). The percent relative standard deviations for all analytes were less than 2.0% for the repeatability and the Intermediate Precision indicating the high precision of the developed analytical method. The low RSD values of repeatability and intermediate precision studies indicate that the method is precise for the simultaneous determination of the active substances (Levocetirizine & Pseudoephedrine). The results of precision parameters was reported in details in Table (5).
Table (5). Results of Precision

<table>
<thead>
<tr>
<th></th>
<th>Repeatability day 1</th>
<th>Intermediate precision day 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levocet.2HCl &amp;</td>
<td>Levocet.2HCl &amp;</td>
<td>Levocet.2HCl &amp;</td>
</tr>
<tr>
<td>Solution</td>
<td>Solution</td>
<td>Solution</td>
</tr>
<tr>
<td>Levocet 2HCl</td>
<td>Levocet 2HCl</td>
<td>Levocet 2HCl</td>
</tr>
<tr>
<td>Pseudo Sul</td>
<td>Pseudo Sul</td>
<td>Pseudo HCl</td>
</tr>
<tr>
<td>101.07</td>
<td>103.29</td>
<td>101.18</td>
</tr>
<tr>
<td>102.51</td>
<td>103.27</td>
<td>102.86</td>
</tr>
<tr>
<td>101.61</td>
<td>103.55</td>
<td>99.97</td>
</tr>
<tr>
<td>100.32</td>
<td>102.56</td>
<td>101.33</td>
</tr>
<tr>
<td>101.66</td>
<td>103.18</td>
<td>99.97</td>
</tr>
<tr>
<td>Mean</td>
<td>101.18</td>
<td>101.42</td>
</tr>
<tr>
<td>SD</td>
<td>0.95</td>
<td>0.95</td>
</tr>
<tr>
<td>%RS</td>
<td>0.94</td>
<td>0.94</td>
</tr>
<tr>
<td>95%C</td>
<td>0.76</td>
<td>0.76</td>
</tr>
<tr>
<td>Lower</td>
<td>100.42</td>
<td>100.17</td>
</tr>
<tr>
<td>Upper</td>
<td>101.94</td>
<td>101.44</td>
</tr>
</tbody>
</table>

4- Conclusion

The developed ion-pairing reversed-phase high performance liquid chromatographic (IP-RP-HPLC) analytical method described above is suitable for the simultaneous determination of levocetirizine dihydrochloride and pseudoephedrine sulfate (or hydrochloride) and stability-indicating, accurate, linear, precise, specific. The method was successfully validated according to the requirements of ICH and the results were acceptable, so, the developed stability-indicating analytical method can be used for routine analysis and stability studies purposes.

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13.
The Role of Transesophageal Echocardiography in Diagnosing Different Types of Atrial Septal Defect
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Abstract
Transesophageal echocardiography has special advantages when investigating the interatrial septum which is imaged perpendicularly without echo dropouts from an esophageal transducer position. The purpose of this prospective study was to compare the diagnostic value of transthoracic (TTE) and transesophageal (TEE) echocardiography in various types of atrial septal defects (ASD).

Between July 2013 and September 2014, twenty one patients (4 men; 17 women; 14 to 64 years of age, mean 29), suspected of having ASD, were studied by TTE and TEE.

TTE demonstrated the ASD in 15 patients (secundum type in 13, primum type in 1 and sinus venosus type in 1). The presence of ASD was suspected in another 3 patients who had left to right shunt but patent foramen ovale (PFO) could not be excluded as the source of the shunt due to very small size of it. In additional 3 patients with signs of moderate right ventricular volume overload, no shunt or defect was detected. TEE demonstrated the defect in 18 patients, but did not reveal any abnormality in the other 3 patient. The defect was of secundum type in 15 patients; two of them had multiple ASD, primum type in 1 and sinus venosus type in 1. Thus, in 3 (16.7 %) of 18 patients with ASD, the atrial septal defect was diagnosed by TEE but not by TTE; two of them had small defects (diameter <5 mm) and one had ASD of intermediate size (>5 - ≤10). In addition, TTE could not diagnose any multiple ASD. Primum-type ASD was diagnosed correctly by both echocardiographic methods. A sinus venosus-type ASD was evident by TEE in 2 patients, of which only one was demonstrated correctly by the transthoracic approach and the other was misdiagnosed as secundum type.

No anomalous pulmonary venous return was seen neither by TTE nor by TEE but was subsequently identified by surgery in one patient. In the remaining three patients, TEE ruled out ASD as the cause of right heart dilatation, and so other causes had to be sought.

In conclusion, compared with TTE, the transesophageal approach is clearly superior in the detection of small secundum-type ASD, multiple ASD and sinus venosus-type ASD.

Key words: ASD, TTE, TEE.

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Management Of Gunshot Injuries Of The Rectum
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Abstract
Objectives: The aim of this study was to analyze the surgical management and associated complications of rectal gunshot injuries in Aleppo University Hospital.
Methods and materials: Between July 2012 and July 2014, 47 patients with gunshot injuries to the rectum were treated at the Aleppo University Hospital. The surgical management of rectal injuries was evaluated, specifically the primary closure of intraperitoneal rectal injuries, and looking at the utilization of diversion with ostomy, distal washout, and presacral drainage in extraperitoneal rectal injuries. Complications were compared between the treatment groups.
Results: Sixteen patients who sustained intraperitoneal rectal injuries were included in this study; the surgical management of them included primary repair in 9 patients (57%), primary repair with proximal diversion in 4 patients (25%), and Hartmann's procedure in 3 patients (18%). Thirty one patients who sustained extraperitoneal rectal injuries were included in this study, the surgical management of them included diversion and presacral drainage in 17 patients (55%), diversion alone in 9 patients (29%), and diversion, distal washout and presacral drainage in 5 patients (16%). Complications were identified in 21% of patients. There were two deaths in the study group.
Conclusion: Intraperitoneal rectal injuries are managed as colon injuries. If the injury is nondestructive, it is managed by primary closure; whereas destructive injury is managed by resection with end colostomy (Hartmann procedure). In this cohort most cases of extraperitoneal rectal injuries have been successfully managed by proximal diversion and presacral drainage.
Keywords: gunshot injury, intraperitoneal rectum, extraperitoneal rectum, primary closure, Hartmann's procedure, proximal diversion, presacral drainage, distal rectal washout.

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Hormonal Therapy (Dosage-Duration) in Infantile Spasm in Syria

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Abstract

Infantile Spasm (IS) is a unique, age-specific disease afflicts infants in the early infancy. A set of parameters and approaches have been developed by many researchers for treating the disease. However, there is insufficient evidence to recommend the optimum dosage and duration of treatment according to the drug type. This paper, concerns with the hormonal therapy of IS using Adrenocorticotropic hormone (ACTH depot) and oral corticosteroid (Predlone) for afflicted infants in Syria. Response to therapy criteria was determined by the complete cessation of spasms and resolution of hypsarrhythmia reported by EEG (Electroencephalograph). Results revealed a superiority of ACTH depot with high dosage (HD-ACTH depot) in comparison with low dosage ACTH depot (LD-ACTH depot) and Predlone. The response rate of our protocol was 80% on HD-ACTH depot, whereas it was 31% and 35% for the LD-ACTH depot and Predlone, respectively. On the other hand, statistical parameters applied in this study pointed out the efficacy of our proposed protocol in developing the response rate at HDACTH depot-treated females by 92.31%, in comparison with LDACTH and Predlone. Our study was applied on patients population referred to Ministry of Higher Education Hospitals during our study period.

Key words: Infantile spasm, EEG, Adrenocorticotropic Hormone.
A Comparative Study To The Forces That Are Generated From Nickel Titanium Closed Coil Springs Over Different Activations Ranges

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Abstract

The aim of this study was to compare the forces that are generated from Nickel Titanium closed coil springs (150 Grams-Medium force) over different activation’s ranges, to evaluate the mechanical behavior of these springs on (50%, 100%, 150%) activation’s distances from their total length. We studied 15 Nickel Titanium closed coil springs produced by (IOS) American company, length 12 mm. We registered the given forces during straining of the springs by using the (Universal Test Machine). We used (paired samples t-test) to compare the registered forces on the studied activation’s distances, and concluded that Nickel Titanium closed coil springs don’t generate an equal force when they are activated to equal activation’s distances, but the doubling of activation range of these springs do not lead to a doubling of force generation, that means “there is nonlinear proportion between the amount of activation and the forces generated from this springs”.

Key words: Closed- Coil Springs, Nickel Titanium, Range of activation.

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Comparison of The Color Stability of Different Esthetic Brackets After Exposed to Tea, Coffee and Cleaning– an In-vitro Study

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** Dept of Fixed Prosthodontics, faculty of dentistry, university of Aleppo
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Abstract

Aim of Study: The present in vitro study was conducted to investigate, evaluate and compare color stability of various esthetic brackets when exposed to coffee, tea, and cleaning.

Materials and Methods: For this study, 60 esthetic brackets for central incisors on the right side were used, of the Roth type, of different brands (IOS, Ortho Technology, Leone). The brackets were stored in two solutions (coffee and tea) at 37°C for 15 days. Spectrophotometric colour measurements for CIE L*, a* and b* were taken by Easy Shade Compact (Vita Zahnfabric, Germany) before and after the brackets were stained.

After the end of the period of Exposure (fifteen days), and measuring the color brackets and calculate color changes, offered brackets for cleaning for five minutes, and was re-measure the color again and calculate the color changes.

Results: Results showed that fibre glass brackets were more color stability than the other brackets after Exposed to tea and coffee. Also results showed that the ceramic brackets became more color stability than the other brackets after cleaning.

Keywords: Cleaning, exposed, color stability, esthetic brackets

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Effects of Food Dyes and Exposure Time on the Color Stability of Esthetic Brackets – an In-vitro Study

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** Dept of Fixed Prosthodontics, faculty of dentistry, university of Aleppo
***Postgraduate student (MSC), Dept of Orthodontics, faculty of dentistry, Aleppo university

Abstract

Aim of Study: The aim of this study was to investigate the effect of food dyes and exposure time on the color stability of esthetic brackets. Materials and Methods: 150 right central incisors esthetic brackets manufactured of three different materials by three brands (IOS, Ortho Technology, Leone) were used in this study. The brackets were stored in five different solutions (tartrazine, carmoisine, brilliant Blue, coffee and tea) at 37°C for 15 days. spectrophotometric colour measurements for CIE L*, a* and b* were taken by easy shade compact (Vita Zahnfabric, Germany).

Results: Results showed that the type of solution and the exposure time significantly influence the level of colour change. Also results showed that coffee and tea are known to cause the greatest staining.

Keywords: Food dyes, exposure time, color stability, esthetic Brackets
Effect of Finishing and Polishing Techniques on The Colour Stability of Composite Restorations

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Abstract

The objective of this study was to compare the effect of two finishing and polishing systems on the colour stability of microhybrid composite restorations. Forty-five composite specimens were made of microhybrid (Charisma) in specific dimensions (5×2mm), then divided into three groups according to finishing and polishing systems as follows:

The First group: No finishing and polishing were made.
The Second group: were finished using finishing bur and Optapolt polishing cups.
Third group (super snap disks) were used for finishing and polishing.

Specimens were soaked in coffee solution for one week and colour was assessed using Vita Easy Shade before and after immersed in coffee solution. L*a*b* values were used to calculate δE values.

Results were statistically analyzed using ANOVA one way and Bonferroni test and the results were:

1- Finishing and polishing has a great effect on colour stability of composite restorations.
2- There was no difference between the two finishing and polishing systems which used in this study on colour stability of composite restorations.

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Accepted 17/11/2014
Traumatic Injuries of Poplitial Artery and Vein

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Abstract

Objectives: To study the etiology, signs and symptoms, pattern of injuries, the implemented treatment strategies, and the mortality rates due to vascular trauma in our population.

Methods: All individuals who presented to the Aleppo University Hospital, with a vascular injury between May 2013 and May 2014 were retrospectively identified from a trauma database.

Result: There were 66 poplitial artery and 50 poplitial vein involved. The most common etiological reason was gunshots (56.7%) followed by fragments (41.8%). These injuries were accompanied by local nerve lesions (17.9%), local bone lesions (58.2%), and injuries to other organs (9%). While concomitant venous injuries were present in (73.1%). Types of vascular injuries were laceration to the vessel wall (15.2%) and loss of vessel wall segment (71.3%). Interposition autogenous saphenous vein graft was the most common type of repair arteries performed (75.8%). Ligation was the most common type of repair veins performed (44%). Edema was a common complication (10.4%) followed by Wound infection (9%). 4 patients required secondary amputation, mostly due to infection, and 4 patients (4.5%) died due to associated injuries. Vascular reconstruction was successful in 60 (89.6%) of cases.

Conclusion: Early re-vascularisation help to save more than 90% limbs with vascular injuries. Extensive soft tissue defect in combined orthopedic and vascular injuries are associated with increased risk of amputation.

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Accepted 19/11/2014
Gastric Plication in Treatment of Obesity
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* Postgraduate Student (Msc)

Abstract

Objectives: Highlightening gastric plication which is one of new surgical procedures for treatment of obesity.

Methods and materials: This study has included 25 patients undergoing laparoscopic gastric plication in Aleppo University Hospital, those patients were between 14-60 years old and their BMI ≥40 or BMI ≥35 with concomitant disease, using prospective study.

Results: The sample has included 24 female patients 96% and one male patient 4%. Those patients were between 14-60 years old with follow up for two years using EWL Measure as an index for losing weight. The outcome was good for 24 patients (96% of the sample) whereas one patient regained weight (4% of the sample).

Conclusion: Obesity is a chronic disease resulting from combination between several genetic and environmental factors. The obesity is necessary to treat and the operation of gastric plication is promising one, its short term results are good according to universal criteria but it is still under study.

Keywords: obesity, gastric plication, BMI, EWL.

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Accepted 25/11/2014
Causes of Penetrating Traumas of Kidney in Aleppo University Hospital
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Abstract
This research was performed on penetrating traumas of Kidney in Aleppo university's hospital in Syrian Arab Republic. Causes of injuries are variable between males and females. These causes are (according to the priority): fragments, gunshots, knife injuries, iatrogenic (nephrostomy-biopsy-during surgery). These causes had planes between ages. There were injuries during surgery in tow classes: under 10 years and between 11-20 years, injuries due to fragments and gunshots were between 21-30 years, causes due to knife injuries were between 31-40 years and injuries due to iatrogenic causes (nephrostomy-biopsy) were above 40 years.

Methods: This research compassed (50) patients in Aleppo University hospital between 2011-2013.

Results: 35 were males and 15 were females. The biggest number of injuries caused by the fragments and gunshots because most of injuries were a result of a war. Causes of penetrating traumas of kidney nowadays are different from others in different places because of the war our community suffer from.

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Accepted 26/11/2014
Formulation and Stability Study of Aqueous Complexes for Cyclodextrin with Minoxidil

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Abstract

We prepared several aqueous formulations of minoxidil by forming a complexes with two types of cyclodextrins (2-hydroxypropyl-β-cyclodextrin and 2,6-dimethyl-β-cyclodextrin) in order to solubilization and stabilization of minoxidil in aqueous media. We proved the former complexes formation by using differential scanning calorimetry (DSC), and the compatibility between the drug and the used excipients in prepared formulation by comparison between DSC curves of minoxidil and used excipients and physical mixtures prepared between minoxidil and these excipients. The assay of minoxidil was done by using high performance liquid cromatography (HPLC). The accelerated stability studies were done for ethanolic and aqueous preparatios of minoxidil at several pH values. It was obtained on stable aqueous pharmaceutical forms during the stability study since the degradation rate was within the specification limits (5%) except the preparation with glycerin which degarated about (15%) that leads to this excipient is incompatible with the studied pharmaceutical formulation.

Keywords: Minoxidil, Cyclodextrin, Inclusion complex, accelerated stability.

Received 28/9/2014
Accepted 1/12/2014
Penetrating Traumas of Kidney

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Abstract

This research was performed on penetrated traumas of Kidney in Aleppo university's hospital in Syrian Arab Republic – this because of spreading of this injury between our patients in the emergency department and its larg concomitancing with the injury of organs had effect on the daily life of the person and this social activity.

Methods: This research compassed (50) patients, who consulted the emergency department in Aleppo University hospital between 2011-2013.

Results: 35 were males and 15 were females. The biggest number of injuries was recorded between the age of (21-30) years. Because the most of the injuries were a result to war. The trauma was in right kidney in 16 patient and in left kidney in 33 patient. The most common symptom was the pain in flank. the Liver injury was the commonest in 15 cases. Kidney traumas were treated conservationly in 11 cases and surgically in 39 cases, 23 cases were completely cured, in 13 cases there were complications, 4 patients died.

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Prevalence of Macrocytosis in Patients with Chronic Obstructive Pulmonary Disease
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Abstract
The MCV is one of the commonly and frequently tests in the hospitals.
Macrocytosis is commonly caused by alcoholic, vitamin B12 and folic acid deficiencies and certain medications, and a few doctors know that Macrocytosis could be present in patients with chronic Obstructive pulmonary disease (COPD).

Aims: Our research aims to study the prevalence Macrocytosis in stable COPD patients, and study its relationship with the lung function.

Material and method: Study was conducted in a Aleppo University hospital from 18\9\ 2013 to 18\9\ 2014, and included 87 stable COPD patients older than 18 years and have been excluded patients a lack of vitamin B12 or folic acid or heavily addicted alcohol, where we take the clinical history and we had a clinical examination, laboratory tests and respiratory volumes, then we analyzed the results statistically.

Results: The study included 87 patients. 20 patients had macrocytosis (23%) (MCV> 94fl) and mean of MCV in all patients was 98.1 fl. There were statistically significant differences in moderate alcohol intake and O2 saturation and HGB and HCT between patients with and without Macrocytosis.

Keywords: Macrocytosis, COPD.
Effect of Fabrication Technique on Marginal Fit Accuracy of Lithium Disilicate Inlay (in-Vitro Study)
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Abstract
Statement of problem: CAD/CAM is an alternative fabrication technique of lithium disilicate inlay. However, there is little information on his marginal accuracy.

Objectives: The purpose of this in vitro study was to evaluate the effect of fabrication technique on the marginal fit of lithium disilicate inlay regarding reducing the ratio of clinically unacceptable measurements of marginal gap.

Materials and Methods: Twenty full anatomic lithium disilicate ceramics inlay fabricated from 2 systems (IPS e.max CAD and IPS e.max Press). the IPS e.max CAD inlay machined using the newly milling unit InLab MC XL, specimens were divided into 2 groups of 10, were evaluated using a light microscope the metal die. Sixty measurements were taken for each specimen.

Results: The obtained data were analyzed statistically by SPSS with K-square test. e.max cad showed significantly smaller (p<.05) ratio of clinically unacceptable measurements than e.max press.

Conclusions: Within the limitations of this study, and based on the criterion of 120 as the limit of clinical acceptability, IPS e.max CAD is recommended.

Key words: Marginal fit, inlay, CAD/CAM

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Investigating the Role and Variations of Some Adherens Junctions Components in Oral Squamous Cell Carcinoma
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Abstract

Background and Objective: Adherence junctions connect epithelial cell each other through its proteins which are mainly composed of E-cadherin and β-catenin. Malignant tumor cells try to release itself from these ligands to be able on invasion and Metastasis. Oral squamous cell carcinoma is an invasive epithelial neoplasm with varying degrees of squamous differentiation, tends to early and invasive metastasis and counts more than 90% of head and neck malignancies.

Materials and methods: E-cadherin and β-catenin expression was compared immunohistochemically between oral squamous cell carcinoma in 25 case (17 male+8 female) ranging between (18-90) years, with mean age of (59) years. They have been divided into 3 groups according to the histological grad. Statistical analysis One way Anova and Pearson Correlation Coefficient were used with p<0.05.

Results: a significant correlation between E-cadherin and β-catenin expression and the histological grad was observed, the intensity of expression decreased as the cancer became more poorly differentiated. Decreased membranous localization and intense cytoplasmic staining were also observed in poorly differentiated.

Conclusion: according to this study we observed a clear alteration in the adherens junctions’ components in oral squamous cell carcinoma. E-cadherin and β-catenin expression decreased as the tumor degree increased, so that we can consider them as prognostic biomarkers for this tumor.

Keywords: Oral squamous cell carcinoma, histologic differentiation, adherence junctions, E-cadherin, β-catenin.
Comparative of the Dimensional Accuracy of Silicone Impression Materials Using the Microscope Archimedean Spiral Provided and Digital Caliper

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ABSTRACT

OBJECTIVE: Silicone has become the most common material used to get the final impression for dentist. That is because they are easy to use, and accurate in reproducing details. In this research, we aim to highlight the role of hydrocolloid in the final impression and its accuracy compared to silicon materials.

PURPOSE: To compare the accuracy of the dimensions between alginate and silicon materials when used for final impressions in crowns and bridges.

MATERIAL AND METHODS: Upper jaw frasaco was used. Vestibular surfaces of left and right canines were prepared. Also, vestibular surfaces of the bilateral first two molars were prepared. Preparation was achieved by Diamond-dent. Opposite measuring surfaces were made smooth and parallel to each other. Silicone impression was made using additional polymerized and replacing frasaco by acrylic model. We used crystal trays to make impressions. 30 alginate impressions was taken, preserved for 15 minutes in a well-sealed container with a wet handkerchief on them. Another 30 silicon impression was made utilizing condensation silicon with two-step technique according to the manufacturer's instructions. Impressions were preserved at room temperature for an hour pouring. Measurement was conducted using a microscope and caliper, taking into account measuring each studied dimension for three times and considering the mean.

RESULTS: There was no statistically-significant difference between the dimensions of the material alginate accuracy and precision dimensions silicone material.

CONCLUSION: The alginate impression was comparable to silicon's in terms of dimensional accuracy for supra-lingival preparations when adhere to the instructions of the manufacturer.

KEYWORDS: impressions, silicone impression materials, Digital Caliper

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A Comparative Study Between Torsional Bond Strengths of Two Hard Chairside Denture Reline Materials before and after Procedure of Microwave Irradiation (In Vitro Study)

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Abstract
Alveolar bone that supports dentures absorbs to varying affects alveolar edge that supports denture absorption to varying degrees, thereby moving the denture for the loss of firmness and stability with its supporting tissues therefore needs to periodically lining.

The aim of study: The goal of research: a comparison between two types of solid direct lining materials with the Acrylic resin of dentures strength before and after exposure to microwave radiation.

Materials and Methods: This study use of two kinds Hard Chairside Denture Reline Material and distributed samples relining solid according to (4) groups, for each material relining, the group first set control group (not exposed to radiation microwave), sterilized the second set before connecting with the material relining for a month three times a week and then linked with material direct solid lining, the third group sterilized after connecting with direct material lining for one month three times a week, while the latter group sterilized before and after connecting with the material relining for one month three times a week, and the measured correlation strength of each sample in each group and paired them with similar groups from other type of relining material.

Results: Excelled acrylic samples linked with GC Reline relining material in the four study groups on the acrylic samples linked with material relining Toukoyama Rebase Fast correlation strength before and after exposure to various sterilization cycles microwave irradiation.

Keywords: acrylic break resistant, microwave irradiation sterilization, lining steel self-sclerosis

Accepted 2014/12/8
The Bronchoscopy Results
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Abstract:
Study objectives: To assess the bronchoscopy diagnostic yield of pulmonary lesions in Aleppo university hospital
Study Design: A retrospective study of bronchoscopies performed between 2011 and 2013.
Our study included (534 cases), male(422)78.5%, average age(51±16) years. The bronchoscopy findings was normal in (150 cases)28%, the pathology report nonspecific inflammation (218 cases)40.8%.

Final diagnosis: The malignant lesions (168 cases) 31.5%, infectious lesions (116 cases) 31.5%, benign non infectious lesions (20 cases)3.7%, traumatic lesions (12 cases) 2.2%.
In the malignant cases male(143)85%, average age 56±12 years, normal bronchoscopy (20 cases)12%. the leading histological cell type was squamous cell carcinoma(66 cases)39%, followed by adenocarcinoma (35cases)20.8%, small cell lung cancer(31)18.5%, metastases(14)8.3%, undifferentiated carcinoma(7)2.4%, lymphoma(5)3%, large cell lung cancer (4)2.4%, carcinoid(3)1.8%, dysplasia(3)1.8% . The sensitivity of bronchoscopy finding (1.2-60.24%), specificity (78.68-98%) .
In the infectious cases, Koch bacillus was the pathogen (96 cases)18%, average age 40.8±17 years, male(70 cases)73%.

Conclusion:
Bronchoscopy is valuable and essential for lung malignancies diagnosis we must use recent bronchoscopic techniques to optimize the diagnostic yield.
Fibreoptic bronchoscopy should be considered complementary to sputum examination in the evaluation of TB suspects, especially in countries where TB infection is common.

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Association of Calcium-Phosphorus Product with Blood Pressure in Dialysis
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Abstract
Background: Hypertension is, with a reported prevalence from 60% to 86%, a major public health problem and is considered a major risk factor for cardiovascular disease. Disorders of mineral metabolism have been linked to vascular calcification and hypertension in dialysis.

Material and method: Ninety-tow hemodialysis patients were included in a cross-sectional study in a dialysis unit during a 12-month period from September 2013 to September 2014. Predialysis and postdialysis BPs. Serum calcium and Phosphorus were routinely measured per dialysis protocol once or twice a month. Serum albumin and PTH levels were usually measured once a month; Hemoglobin was measured on average twice a month.

Results: Linear regression analysis was done between averages of calcium and phosphorus (ca × ph) product and blood pressures (BPs). Ca × ph was significantly associated with predialysis and postdialysis SBP, DBP, MAP and PP. The findings in our study suggest that in the subgroup with Ca×ph >50, there is a significant link between increased risk of calcification and hypertension.

Conclusion: In this study we demonstrated a strong association between ca×ph with predialysis and Postdialysis MAP, PP, SBP and DBP. The importance of the relationship between ca×ph and hypertension seem to occur when the product is >50, reflecting the role of vascular calcification in the physiologic process.

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Hepatitis C and Renal Failure

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Abstract

Objectives: To study the frequency of HCV infection among renal failure patients.

Methods: A total of 152 blood samples were studied of renal failure patients who were referred to microbiology laboratory of Aleppo University Hospital and 30 subjects as control from Sep 2013 to May 2014. All samples tested for anti HCV antibodies using a commercial second generation enzyme linked immunosorbent assay (ELISA).

Results: Among the 152 clinical specimens included in this study, anti HCV antibodies were detected in 44.7%, and in control group 6.7%. The majority of positive anti HCV antibodies cases were surgical patients and blood transfusion patients.

Conclusion: HCV infection occurs more often in renal failure patients and special hemodialysis patients.

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Color Verification of Metal Ceramic and All Ceramic Crowns in Fixed Prostheses
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Abstract
Introduction: Color conception of fixed prosthesis is considered as one of the most difficulties faced in modern dentistry, with the increase in esthetic demands of the patient, and the visual characteristic insulation which the natural teeth have.

Purpose: The purpose of this study was to test the capability of the dental technician to produce metal ceramic and all ceramic restorations match the color sent from the dentist.

Materials and methods: Eleven young patient were selected for a restoration of a single upper incisor. Two crowns were fabricated for each subject, the first crown was made of a metal ceramic with buccal ceramic shoulder and the second was an all ceramic crown type IPS-e.max. Color selection was done using A-D Shade Guide by eight prosthodontists don’t suffer from colorblindness. The color agreed for each case was sent to a technician who was known for good work and experience. Vita Easy Shade Compact used to measure the color of middle third of the contralateral target tooth of each subject, shade tabs and fabricated crowns. Prosthodontist evaluated the color of crowns (just the middle third) visually in comparing with the contralateral target tooth and corresponding shade tabs, the \( \Delta E \) values between the natural teeth and the crowns, and between the shade tabs and the corresponding crowns were calculated for each case.

Results: There was a good harmony in results of metal ceramic and all ceramic crowns’ color evaluation (\( P\)-value< 0.05, but they were not color satisfied,

Keywords: Vita Easy Shade, all ceramic prostheses, metal ceramic prostheses, color matching.

where a distinct differences from shade tabs selected to match and from the contralateral target tooth (just for the middle third) were denoted, as to prosthodontists evaluation and Easy Shade measurements (\( \Delta E >3.7 \)).
**Conclusion:** dental technician was not capable of production of a metal ceramic or an all ceramic crown matches the shade tab selected to match, and all crowns were not suitable for cementation without color modification. The best color was achieved when the dental technician modified and added dyes clinically.
Prevalence of Hepatitis C Antibodies in Renal Failure Patients

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Abstract

Objectives: To study the frequency of HCV infection among blood transfusion patients.

Methods: A total of 115 blood samples were studied of renal blood transfusion patients who were referred to microbiology laboratory of Aleppo University Hospital and 67 subjects as control from Nov 2013 to Apr 2014. All samples tested for anti HCV antibodies using a commercial second generation enzyme linked immunosorbent assay (ELISA).

Results: Among the 115 clinical specimens included in this study, anti HCV antibodies was detected in 54.78%, and in control group 10.44%. The majority of positive anti HCV antibodies cases were hemodialitic patients and surgical patients.

Conclusion: HCV infection occurs more often in blood transfusion patients, specially hemodialitic patients and surgical patients.

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Association of Hyperphosphataemia with Blood pressure in Non-diabetic hemodialysis patients
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Abstract
Background: Hypertension is considered a major risk factor for cardiovascular disease which is a major cause of morbidity and mortality in haemodialysis patients. The aim of the present study was to analyze the relationships between serum phosphorus levels and hypertension in ESRD patients on haemodialysis.

Methods: Twenty-four non-diabetic haemodialysis patients were included in a cross-sectional study in a dialysis unit during a 12-month period from September 2013 to September 2014. Predialysis and postdialysis BPs, Serum phosphorus was routinely measured per dialysis protocol once or twice a month. Patients were separated arbitrarily into two groups, i.e. with predialysis serum phosphate < 2 mmol/l (‘normal’ phosphate) and, serum phosphate ≥ 2 mmol/l (‘high’ phosphate).

Results: The findings in our study suggest that in the second group there is a significant increased risk of hypertension. Hyperphosphataemia was significantly associated with predialysis SBP, DBP, MAP and postdialysis SBP.

Conclusion: These findings suggest that, in stable ESRD patients on haemodialysis, hyperphosphataemia is associated with increased BP. These could favour the development of cardiovascular complications and contribute to high cardiovascular morbidity and mortality.

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Prevalence of Dyspepsia in Patients with Liver Cirrhosis

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Abstract

Dyspepsia is a frequent complaint in cirrhotic patients, although does not affect survival, it is responsible for substantial health care costs and significantly affects quality of life and nutrition. The aim of the study was to evaluate the prevalence of organic and functional dyspepsia in patients with liver cirrhosis and the symptomatology of this disease and its association with severity of hepatic cirrhosis.

One hundred twenty three patients with liver cirrhosis were included (58 males and 65 females) mean age 55.9. Seventy six patients complained of dyspeptic disorders (61.78%). An organic cause of symptoms could not be identified in 28 patients (22.76%) whereas the following were identified as the causes of organic dyspepsia in the remaining 48 patients (39.2%). In order of frequency: congestive gastropathy (30.08%), gastric and duodenal ulcers (17.57%) and gallbladder stones (11.38%), lastly a combination of at least tow these morbid conditions was found in 24 patients (19.05%).

We found that post prandial distress syndrome was higher in patients with functional dyspepsia 82.14% vs 47.91% in patients with organic dyspepsia p< 0.05, while epigastric pain syndrome was higher in patients with organic dyspepsia 33.3% vs 7.41% in patients with functional dyspepsia p<0.05. The two syndromes were higher in organic dyspepsia 25% vs 10.71% in patients with functional dyspepsia p<0.05.

We found that organic dyspepsia was higher in patients with hepatic compensation 77.7% vs 61.19% in patients with hepatic decompensation. While functional dyspepsia was higher in patients with hepatic decompensation 41.79% vs 22.2% in patients with hepatic compensation p<0.05.

Key wordes Organic dyspepsia, functional dyspepsia, liver cirrhosis, postprandial distress syndrome, epigastric pain syndrome

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Sero Prevalence of CMV, Rubella of Pregnant Women

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Abstract

Objectives: To study the prevalence of rubella and cytomegalovirus (CMV) infections among pregnant women.

Methods: A total of 60 blood samples for pregnant women and 30 for not pregnant women were investigated for rubella and CMV referred to microbiology laboratory of Aleppo University Hospital from Jun 2013 to Jun 2014. IgM and IgG antibodies were assayed by the Enzyme Linked Flourescent Assay ILFA (Vidas).

Result: Rubella IgG seropositivity were found in 57 patients (95%) with no IgM seropositivity. CMV IgG seropositivity were found in 60 patients (100%) with no IgM seropositivity.

Conclusion: High seropositivity rates for rubella and CMV indicate that most of the women were exposed to these viruses before child-bearing age.

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Sero Prevalence of Toxoplasma in Pregnant Women

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Abstract

Objectives: To study the prevalence of *Toxoplasma gondii* infections among pregnant women.

Methods: A total of 60 blood samples for pregnant women and 30 for no pregnant women were investigated for *Toxoplasma gondii* referred to the microbiology laboratory of Aleppo University Hospital from Jan 2013 to Jun 2014. IgM and IgG antibodies were assayed by the Enzyme Linked Fluorescent Assay ILFA (Vidas).

Result: *Toxoplasma gondii* IgG seropositivity were found in 44 women (73.3%) and 3 (5%) were positive for IgM. No significant relationship was found between the seroprevalence of *T. gondii* infection and level of education and life, residence area, history of abortion and gestational age.

Conclusion: The rate of *Toxoplasma gondii* IgM positive was low; however, a large number of the studied population were IgG positive, indicative of having a past exposure to *Toxoplasma* parasite.