

Original article

Effects of Paracetamol, Amoxicillin, and their Combination on Male Rabbit Body and Organs Weight

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ABSTRACT

The administration of pharmaceuticals such as paracetamol (PAR) and amoxicillin (AMO) has been linked to physiological changes in animals. While these drugs are widely utilized for their therapeutic benefits, their potential effects on body and organ weights are not fully understood. Male rabbits were divided into four groups a control group, a group treated with PAR, a group treated with AMO, and a group receiving both drugs PAR+AMO. Body weight changes were monitored weekly, and organ weights (liver, lungs, heart, kidneys, testes, and brain) were measured at the end of the trial. Data were statistically analyzed, with significance set at $p < 0.05$. Body weight changes were observed across all treatment groups. In the control group, there were gradual weight increase from 1839 ± 136.20 g to 1975 ± 89.94 g, remaining consistent throughout the trial. While in the PAR group, we observed initial weight loss from 1667 ± 43.83 g to 1584 ± 31.69 g in week one, followed by recovery and reaching 1860 ± 26.48 g by week five. In the AMO group, there were a minor initial weight loss, followed by steady gains peaking at 2028 ± 12.02 g in week four, slightly decreasing to 2007 ± 4.97 g in week five. In the PAR+AMO group, we reported fluctuations in weight, starting at 1857 ± 52.43 g, peaking in week one (2001 ± 94.50 g), and ending at 1900 ± 92.61 g in week five. Organ weight analysis revealed significant changes. Liver and Lungs were notable increases in the PAR (73.214 ± 5.006 g liver; 8.356 ± 0.663 g lungs) and AMO groups (76.250 ± 0.364 g liver; 6.650 ± 0.030 g lungs). Combination therapy moderated these effects. Other Organs such as kidney, heart, brain, and testes weights showed no significant alterations ($p > 0.05$) across the groups. In conclusion, this study highlights the differential impact of PAR and AMO, individually and in combination, on body and organ weights in male rabbits. While PAR and AMO caused notable changes in liver and lung weights, combination therapy appeared to moderate these effects. Body weight fluctuations were observed across all groups, emphasizing the need for further investigation into the mechanisms underlying these physiological responses to pharmaceutical interventions.

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INTRODUCTION

Paracetamol, often known as acetaminophen in the US and Canada, is the most commonly used analgesic and antipyretic medication worldwide. Its widespread use is due to its capacity to effectively reduce temperature and treat mild to moderate discomfort, as well as its generally positive safety profile when taken at therapeutic levels [1]. Paracetamol

was originally synthesized in the late 19th century, and its clinical use began in the mid-20th century. It was first created from coal tar, a byproduct of the coal industry, but advances in pharmaceutical chemistry have made it possible to synthesize it using more complex chemical procedures. The drug's introduction signaled a significant shift in the management of pain by providing an alternative to salicylates and other non-steroidal anti-inflammatory drugs (NSAIDs), which were associated with higher risks of gastrointestinal bleeding [2].

Unlike NSAIDs, the exact mechanism of action of paracetamol is not entirely known. NSAIDs usually function by blocking the enzymes known as cyclooxygenase (COX). It is believed that suppression of COX-3 or interaction with serotonergic pathways may be the primary mechanisms by which paracetamol generates its analgesic effects. Additionally, it has been suggested that paracetamol may influence the endocannabinoid system to produce analgesic effects [3].

Paracetamol can be used to treat a variety of conditions, including fever, headache, tooth pain, and musculoskeletal discomfort. It is commonly advised for people for whom NSAIDs are contraindicated, such as those with gastrointestinal issues, cardiovascular illnesses, or aspirin sensitivity. Its potential to improve pain management and potentially reduce the dosage of opioids required, which minimizes the risks of opioid therapy, is further demonstrated by its usage in combination medications, such as those that contain opioids [4].

Amoxicillin is a broad-spectrum β -lactam antibiotic that is essential for treating a variety of bacterial illnesses. It is a member of the penicillin family and has been used extensively in therapeutic settings due to its affordability, safety record, and efficacy. Since its invention in the early 1970s, amoxicillin has been crucial in the fight against bacterial infections, especially those that result in respiratory, urinary, and gastrointestinal illnesses [5]. Amoxicillin was developed in response to the need for a penicillin derivative with a greater range of activity and improved oral absorption. Beecham Research Laboratories developed amoxicillin in the late 1960s, and it was initially approved for use in medicine in 1972. It quickly became the most prescribed antibiotic in the world due to its ability to treat a wide range of infections with few adverse effects that are sometimes associated with other antibiotics [6].

Amoxicillin can be used to treat a wide range of illnesses, including helicobacter pylori-associated gastritis, pneumonia, streptococcal pharyngitis, acute otitis media, and urinary tract infections. Because of its excellent pharmacokinetic profile which includes wide tissue distribution and good absorption from the gastrointestinal system it is a well-liked choice in both outpatient and inpatient settings. Additionally, amoxicillin-clavulanate combinations have become more effective by avoiding resistance mechanisms such as β -lactamase production that are present in some bacterial strains [7]. The widespread use of amoxicillin has unavoidably led to the emergence of resistant bacterial strains. The development of β -lactamase, which may hydrolyze the β -lactam ring of amoxicillin and render it useless, is one of the primary mechanisms of resistance in bacteria.

To combat this and restore its capacity to treat resistant bacteria, amoxicillin is commonly used in combination with clavulanic acid, a β -lactamase inhibitor. However, the development of antibiotic resistance remains a significant issue that necessitates cautious amoxicillin use and ongoing observation [8]. This study aimed to evaluate the effects of paracetamol, amoxicillin, and their combination on the body weight and organ weights of male rabbits over twelve weeks.

METHODS

Materials

Amoxicillin and Paracetamol (99% pure) were purchased from Middle East Pharmaceutical and Cosmetics Laboratories Co.LTD. The experiment's additional substances were all bought from reputable commercial vendors.

Experimental animals

From nearby certified farms, twenty healthy adult male rabbits weighing 1900 g were acquired. These rabbits were housed in a room that was appropriate for the trial duration and furnished in accordance with US-EPA 2004. The rabbits were kept in accordance with the US-EPA2004 for animal care and the Libyan Ministry of Agriculture's principles and guidelines. Each rabbit was kept in a suitable steel cage with a temperature between 22 and 26°C, a humidity level between 40 and 70%, and a clean environment with a 12-hour cycle of light. For the course of the entire trial, a proper diet consisting of clean water and balanced feed has been supplied.

The animals received the following treatment after being randomly assigned to four groups, each consisting of five rabbits. Group 1: Amoxicillin (15 mg for rabbits) (8 mg/kg body weight) was administered orally to each rabbit every day for 14 days. Group 2. For 14 days, each rabbit received oral dosage of 50 mg of paracetamol (24 mg/kg body weight) every day, For 14 days, each rabbit. Group 3. Received oral dose of Amoxicillin (15 mg) (8 mg/kg body weight) and

Paracetamol (50 mg/kg body weight) every day. Group 4. Maintained as a control, administered orally for 14 days with 8 milliliters of purified water.

Experimental design

All rabbit groups were observed over the course of the twelve-week trial period, which included two weeks of therapy and twelve weeks without treatment. Weekly rabbit weights were noted, and at the conclusion of the experiment, the rabbits were killed to extract blood and rinse the main organs (heart, brain, liver, kidney, and testes) in saline solution (0.9% NaCl), dry them on filter paper, and weigh each one separately. The relative organ weight (organ weight: body weight) was then computed.

Collection of samples

Body weight of each animal was recorded weekly throughout the 12-week of the experimental period. The weight measurements were carried out in the morning before access to feed and water. A weight of organs was also recorded.

Statistical analysis

Minitab software (version 17) or GraphPad Prism 8 were used for statistical analysis as needed. Following the identification of a normal distribution in the data, an ANOVA analysis using the Tukey multiple comparison test was performed to obtain a significance threshold of $P < 0.05$.

RESULTS

Table 1 shows the body weight values of male rabbits given either PAR, AMO, or both throughout a five-week period. By the fifth week, the control group's rabbits' body weight had risen gradually from 1839 ± 136.20 g at zero week to 1975 ± 89.94 g.

Throughout the trial, this group's body weights were largely constant, demonstrating a statistically significant difference from the treatment groups ($p < 0.05$). PAR-treated rabbits exhibited a reduction in body weight from 1667 ± 43.83 g at zero week to 1584 ± 31.69 g in the first week. But in the weeks that followed, the body weight increased, and by the fifth week, it was 1860 ± 26.48 g.

Comparing the rabbits' body weight to the control, the substantial weight changes show that PAR therapy had an impact ($p < 0.05$). The rabbits in the AMO group had a minor loss in body weight during the first week, but then a steady gain that peaked in the fourth week at 2028 ± 12.02 g, before declining slightly to 2007 ± 4.97 g in the fifth week. These body weight changes were substantial ($p < 0.05$) when compared to the control group. The body weight of rabbits treated with the PAR+AMO increased from 1857 ± 52.43 g at zero week to 2001 ± 94.50 g in the first week, then dropped to 1666 ± 157.58 g in the second week, and then fluctuated in the weeks that followed, reaching 1900 ± 92.61 g in the fifth week. Due to the combined action of the medicines, these changes were substantially different from those in the control group ($p < 0.05$). All treatment groups showed notable differences in body weight from the control group during the course of the trial, demonstrating the effects of amoxicillin, paracetamol, and their combination on the regulation of body weight in male rabbits.

Table 1. BW values of male rabbits given paracetamol, amoxicillin, and their combination.

Groups	Zero week Mean± SEM	1 st week Mean± SEM	2 nd week Mean±SEM	3 rd week Mean ±SEM	4 th week Mean±SEM	5 th week Mean±SEM	PValue
Control	1839 ± 136.20^b	1899 ± 170.76^b	1866 ± 146.88^b	1869 ± 151.10^b	1865 ± 74.99^b	1975 ± 89.94^b	0.000
Paracetamol (PAR)	1667 ± 43.83^a	1584 ± 31.69^a	1708 ± 34.68^a	1809 ± 10.72^a	1910 ± 43.00^a	1860 ± 26.48^a	
Amoxicillin (AMO)	1826 ± 7.05^a	1704 ± 6.40^a	1880 ± 7.59^a	1985 ± 6.89^a	2028 ± 12.02^a	2007 ± 4.97^a	
PAR+AMO	1857 ± 52.43^b	2001 ± 94.50^b	1666 ± 157.58^b	1918 ± 59.58^b	1893 ± 106.12^b	1900 ± 92.61^b	

Means \pm SE are used to express values; each treatment group has $n = 5$. $P < 0.05$ indicated a significant difference between mean values within a row that did not share a common superscript letter (a, b, c)

Table 2 shows the values of the organ weights of male rabbits treated with AMO, PAR, and their combination PAR+AMO. The liver weight of the PAR group was substantially larger at 73.214 ± 5.006 g ($p < 0.05$) than that of the control group, which was 60.400 ± 0.707 g. The liver weight of the AMO group was 76.250 ± 0.364 g, which was likewise substantially different from that of the control group ($p < 0.05$). The liver weight of the combined therapy PAR+AMO was 59.600 ± 4.589 g, which was more in line with the control group. 5.000 ± 0.637 g was the lung weight of the control

group. The AMO group's lung weight was 6.650 ± 0.030 g, but the PAR group's increased to 8.356 ± 0.663 g. Using PAR+AMO together, the lung weight was 6.960 ± 0.589 g. ($p < 0.05$) The group differences were statistically significant. Between the control group and the PAR group, the heart weight values ranged from 3.200 ± 0.200 g to 3.876 ± 0.094 g, with no discernible differences between the groups. With a p-value of 0.019, there was some statistical difference between the treatments.

The kidney weights of the PAR and AMO groups were 12.136 ± 1.006 g and 11.605 ± 0.011 g, respectively, whereas the control group's weight was 10.240 ± 0.371 g. These differences were not statistically significant. The kidney weight of the PAR+AMO group was 11.590 ± 0.541 g, and their p-value was 0.185. There was no significant difference in the weights of the testes across the groups; the control group weighed 4.432 ± 0.486 g, while the PAR, AMO, and PAR+AMO groups weighed between 3.370 ± 0.010 g and 4.81 ± 0.41 g ($p = 0.069$). There was no significant difference in the rabbits' brain weights across the groups; the control group weighed 4.828 ± 0.527 g. Among the other groups, the PAR group weighed 4.970 ± 0.050 g, whereas the PAR+AMO group weighed 5.49 ± 0.936 g ($p = 0.815$). In comparison to the control group, the administration of paracetamol, amoxicillin, and their combination had a substantial impact on the weights of several organs, especially the liver and lungs. Other organs including the brain, kidneys, heart, and testes, however, did not exhibit any appreciable alterations in response to the various therapies.

Table 2. Organ weight values in male rabbits given paracetamol, amoxicillin, and their combination.

Groups	Liver Mean \pm SEM	Lung Mean \pm SEM	Heart Mean \pm SEM	Kidney Mean \pm SEM	Testes Mean \pm SEM	Brain Mean \pm SEM
Control	60.400 0.707 ^{a±}	5.000 0.637 ^{a±}	3.200 0.200 ^{a±}	10.240 0.371 ^{a±}	4.432 0.486 ^{a±}	4.828 0.527 ^{a±}
Paracetamol (PAR)	73.214 5.006 ^{ab±}	8.356 0.663 ^{ab±}	3.876 0.094 ^{a±}	12.136 1.006 ^{a±}	4.81 0.41 ^{a±}	4.970 0.050 ^{a±}
Amoxicillin (AMO)	76.250 0.364 ^{b±}	6.650 0.030 ^{ab±}	3.240 0.013 ^{a±}	11.605 0.011 ^{a±}	3.370 0.010 ^{a±}	5.290 0.007 ^{a±}
PAR+AMO	59.600 4.589 ^{b±}	6.960 0.589 ^{b±}	3.767 0.251 ^{a±}	11.590 0.541 ^{a±}	4.880 0.521 ^{a±}	5.49 0.936 ^{a±}
P value	0.013	0.007	0.019	0.185	0.069	0.815

Means \pm SE are used to express values; each treatment group has $n = 5$. $P < 0.05$ indicated a significant difference between mean values within a row that did not share a common superscript letter (a, b, c).

DISCUSSION

The current study shows that over the twelve weeks of the trial, treating rabbits with a combination of amoxicillin and paracetamol caused a certain mortality rate. Diarrhea observed in the experimental animals may be the cause of this death. This was consistent with the findings of previous study [9], which showed that amoxicillin or its acidic metabolite had similar effects on other species. Insomnia and appetite loss were noted as clinical symptoms of every therapy. Additionally, rabbits treated with paracetamol plus the cocktail displayed cracked lips and mouth swelling, particularly during the fourth week of the trial. The considerable skin discomfort noted in the current investigation could be related to this.

It is evident that the control group grows properly, as evidenced by the fact that their body weight grew at the study's conclusion. Alternatively, the therapies growth was slower in the amoxicillin, paracetamol, and combination group than in the control group, demonstrating how the medicines affected body weight. Compared to amoxicillin and paracetamol, the mixture's effect on body weight reduction was more noticeable. This implies that poisoning has a synergistic impact. A substantial difference between the control group's and the treatments' effects was shown by statistical analysis; the p-value was less than 0.05. The control group had the greatest weight, whereas the combination had the lowest weight, according to a comparison of the data at the end point. Furthermore, all treatments raised liver weight more than the control sample, according to the effects of the treatments on liver weight. The results are explained by the possibility that liver toxicity caused by amoxicillin and paracetamol seriously damaged the liver cells. Our findings concur with [10]. They discovered that amoxicillin affected the levels of lipid peroxidation in different organisms as well as the activities of catalase (CAT) and superoxide dismutase (SOD) [10]. Additionally, it was discovered by previous study [11] that amoxicillin dose-dependently affects ameloblast activities, particularly during the maturation phase, resulting in the production of hypomineralized enamel with quantitative and orqualitative abnormalities in mice. The findings of previous study [12] showed that the liver is more susceptible than other organs to the toxicity of diuron, provided additional support for our findings. Furthermore, it may be proposed that the liver produces some metabolites that are more toxic than amoxicillin as a result of metabolic reactions or detoxification of the drug's effects. The same thing was

noted by previous study [9]. However, compared to the control group, the weight of the liver rose with the use of paracetamol and mixture therapies, which may indicate hepatomegaly. For additional cases, similar findings were made [13]. Additionally, all treatments significantly decreased the rabbits' heart weight. These findings are explained by the fact that paracetamol and/or amoxicillin react with heart cells, disrupting normal development. Recently, several cases have revealed reduced heart weight [14]. Conversely, the therapies caused the kidney's weight to drop below that of the control group, which suggests nephrotoxicity [15]. Our findings are consistent with those of previous study [16], who showed that paracetamol and/or a combination of paracetamol and amoxicillin can cause nephrotoxicity.

CONCLUSION

This study highlights the substantial impact of paracetamol, amoxicillin, and their combination on body and organ weights, particularly the liver and lungs. The findings underscore the importance of monitoring drug interactions and their physiological effects in therapeutic applications. The study revealed that paracetamol, amoxicillin, and their combination significantly affected the body and organ weights of male rabbits. The individual and combined administration of these drugs induced observable toxic effects, potentially linked to altered physiological processes and organ function. This highlights the importance of careful dosing and consideration of drug interactions to mitigate adverse outcomes. Further research is recommended to elucidate the underlying mechanisms and assess protective strategies against such toxicity.

Conflict of interest. Nil

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تأثيرات الباراسيتامول والأموكسيسيلين ومزيجهما على وزن جسم وأعضاء ذكور الأرانب

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المستخلص

تم ربط إعطاء المستحضرات الصيدلانية مثل الباراسيتامول و المضاد الحيوي الأموكسيسيلين بالتغيرات الفسيولوجية في الحيوانات. في حين يتم استخدام هذه الأدوية على نطاق واسع لفوائدها العلاجية، إلا أن تأثيراتها المحتملة على أوزان الجسم والأعضاء ليست مفهومة تمامًا. تم تقسيم الأرانب الذكور إلى أربع مجموعات التحكم، ومجموعة عولجت بالباراسيتامول، ومجموعة عولجت بالأموكسيسيلين، ومجموعة تألفت كلا العقارين الباراسيتامول والاموكسيسيلين. تمت مراقبة تغيرات وزن الجسم أسبوعيًا، وتم قياس أوزان الأعضاء (الكبد والرئتين والقلب والكلى والخصيتين والدماغ) في نهاية التجربة. تم تحليل البيانات إحصائيًا، مع تحديد الأهمية عند $p < 0.05$. تم ملاحظة تغيرات في وزن الجسم في جميع مجموعات العلاج مجموعة التحكم زيادة تدريجية في الوزن من 136.20 ± 1839 جرام إلى 89.94 ± 1975 جرام، وظلت ثابتة طوال التجربة. مجموعة الباراسيتامول تم فقدان الوزن الأولي من 43.83 ± 1667 جرام إلى 31.69 ± 1584 جرام في الأسبوع الأول، تلا ذلك التعافي والوصول إلى 26.48 ± 1860 جرام بحلول الأسبوع الخامس. مجموعة الاموكسيسيلين تم فقدان الوزن الأولي البسيط، يليه مكاسب ثابتة بلغت ذروتها عند 12.02 ± 2028 جرام في الأسبوع الرابع، ثم انخفضت قليلاً إلى 4.97 ± 2007 جرام في الأسبوع الخامس. مجموعة الباراسيتامول والاموكسيسيلين حدثت تقلبات في الوزن، بدءًا من 52.43 ± 1857 جرام، وبلغت ذروتها في الأسبوع الأول (94.50 ± 2001 جرام)، وانتهت عند 92.61 ± 1900 جرام في الأسبوع الخامس. كشف تحليل وزن الأعضاء عن تغييرات كبيرة في الكبد والرئتين نلاحظ زيادات ملحوظة في مجموعات الباراسيتامول (73.214 ± 5.006 جم الكبد؛ 0.663 ± 8.356 جم الرئتين) ومجموعات الاموكسيسيلين (76.250 ± 0.364 جم الكبد؛ 0.030 ± 6.650 جم الرئتين). خفف العلاج المركب من هذه التأثيرات. لم تظهر أوزان الكلى والقلب والدماغ والخصيتين أي تغييرات كبيرة ($0.05 < \text{ص}$) عبر المجموعات. وفي الختام، تسلط هذه الدراسة الضوء على التأثير التفاضلي للباراسيتامول والاموكسيسيلين، بشكل فردي وبالاشتراك، على أوزان الجسم والأعضاء لدى ذكور الأرانب. وفي حين تسبب الباراسيتامول والاموكسيسيلين في حدوث تغييرات ملحوظة في أوزان الكبد والرئة، بدا أن العلاج المركب يخفف من هذه التأثيرات. ولوحظت تقلبات في وزن الجسم في جميع المجموعات، مما يؤكد الحاجة إلى مزيد من التحقيق في الآليات الكامنة وراء هذه الاستجابات الفسيولوجية للتدخلات الصيدلانية.

الكلمات المفتاحية: أموكسيسيلين، باراسيتامول، الجسم، الوزن، الأرانب